Instruments and Accessories

User Manual

PN 550675-06 Rev. G 2014. 04

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CE 0543

INTUITIVE SURGICAL®

Rx only

Contents

End of section

1 General Information

1.1 How to Use this Manual

This manual provides limitations on use and instructions for use for instruments, accessories and components used with the *da Vinci*®, *da Vinci*® *S*™, and *da Vinci*® *Si*™ surgical systems. It is not a reference for surgical techniques. It is intended to be kept with the *da Vinci* Surgical System with which it is used. For cleaning, disinfection, and sterilization of reusable instruments, accessories, and components, refer to the Reprocessing Instructions (PN 550875).

Note: Read Knowing What Applies – Organization of this Manual (page 1-1) to understand what portions of this manual apply to any specific instrument or accessory. If information specific to an instrument or accessory is not supplied in this manual, *Intuitive* supplies it with that instrument or accessory.

WARNING: Be sure to read and understand all information, particularly caution and warning information, found in the applicable user manuals before using these products. Failure to properly follow all instructions, including instructions supplied with accessory devices like generators and the applicable user manuals for the *InSite* Vision System, *da Vinci, da Vinci S* and/or *da Vinci Si* Surgical System may lead to injury and result in improper functioning of the device.

Note: Proper surgical procedure and techniques are the responsibility of the medical professional. Procedures described herein are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the procedure based on their own medical training and experience, the type of surgical procedure, and the type of systems utilized.

Knowing What Applies – Organization of this Manual

- This General Information chapter applies to all instruments and accessories supplied by *Intuitive Surgical*.
- Chapter 2 provides general information that applies to all EndoWrist® Instruments. All instruments supplied by *Intuitive Surgical* for use with any *da Vinci* Surgical System are *EndoWrist* instruments, including scissors, scalpels, graspers, needle drivers, clip appliers, monopolar and bipolar electrocautery instruments, and any specialty instruments like the *EndoWrist* Stabilizer.
- Chapter 3 provides general information that applies to all cautery instruments, generator settings and energy activation cables.
- Chapters 4 through 18 provide information specific to particular *EndoWrist* instruments. Read the chapter heading or table of contents to identify the applicable instruments for each chapter.
- Chapters 19 through 23 provide information related to cannulae and accessories used with them, like obturators, reducers, seals and cannula mounts. Read the chapter heading or table of contents to identify the applicable accessories for each chapter.
- Chapter 24 provides information about the *da Vinci* and *da Vinci S* Light Guide.
- Chapter 25 provides information about *Intuitive Surgical* Sterilization Trays.

1.2 Declaration

CE
0543

Intuitive Surgical EndoWrist® instruments and accessories bear the CE Mark to indicate their conformity with the provisions of the 93/42/EEC Medical Devices Directive.

Note: Some items may be manufactured by an OEM partner and may bear their CE mark. Such items are specified in the relevant sections.

Contact Information

For Customer Service and Reporting of Complaints or Adverse Events

Use the following information for customer service, including ordering, reporting complaints or adverse events, and general information regarding *Intuitive Surgical* or our products and services.

In the U.S.

Intuitive Surgical, Inc.
1266 Kifer Road
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For Technical Support

If the system requires maintenance or service, please call our Technical Support line. In the US, call 1-800-876-1310, where phones are staffed 24 hours a day, seven days a week. In Europe, call +41.21.821.2020.

If you have questions regarding the use, cleaning, sterilizing or storing of *Intuitive Surgical* devices used with the *Intuitive Surgical* Endoscopic Instrument Control System, please contact *Intuitive Surgical* Customer Service at the phone number above.

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Note: Manufacturer and EC representative information may vary for some items manufactured by an OEM partner. Such items are specified in the relevant sections.

1.3 Limitation on Use – Limited License

Intuitive Surgical instruments and accessories are provided pursuant to a limited license to use only with the *Intuitive Surgical da Vinci, da Vinci S,* and *da Vinci Si* Surgical System (Endoscopic Instrument Control System). Upon expiration of the instrument's or accessory's programmed

maximum number of uses, this limited license expires. Any other use of *Intuitive Surgical* instruments or accessories, whether before or after instrument or accessory expiration, including repair, refurbishment, remodeling or reconditioning, is strictly prohibited.

1.4 General Precautions and Warnings

WARNING: Read all instructions carefully. Failure to properly follow instructions may cause improper functioning of the device.

Note: Only surgeons who have developed adequate robotic skills to perform the tasks associated with each procedure and who have received specific training provided by Intuitive Surgical, Inc., in the use of the *da Vinci, da Vinci S* or *da Vinci Si* surgical systems should use the system. Training provided by *Intuitive Surgical* is limited to the use of the *da Vinci*, *da Vinci S* and *da Vinci Si* surgical systems and does not replace the necessary medical training and experience required to perform surgery.

Note: Instruments and accessories contain metal components. Ensure that patients do not have metal allergies.

Non-sterile

Note: *Intuitive Surgical* devices ship non-sterile unless otherwise indicated in the device's labeling. Clean and sterilize reusable devices before each use, unless a particular device is not used within the sterile field.

1.5 General Instructions

Proper Care and Handling

Proper care and handling is essential for satisfactory performance of surgical instruments and accessories. Examine the instrument or accessory—including all of its components—thoroughly before and after each use. If any abnormality is found, do not use it. Use the device for its intended purpose only.

Do not expose to X-rays, radioactive rays or strong electromagnetic waves. Otherwise, the instrument may be damaged, making it unrecognizable to the system.

Storage Between Uses

After removing products from their packaging, store *Intuitive Surgical* instruments, accessories or components in a clean, dry, dark place. Care must be taken to protect the instrument tips from damage.

Disposal

When disposing of *Intuitive Surgical* instruments, accessories, or any of their components, follow all applicable national and local laws and guidelines.

End of section

2 EndoWrist® Instruments

Note: *EndoWrist* instruments ship non-sterile. Clean and sterilize reusable *EndoWrist* instruments before use.

2.1 Introduction

Intended Use

EndoWrist Instruments, including scissors, scalpels, forceps, needle drivers and electrocautery are intended for endoscopic manipulation of tissue, including: grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery and suturing.

Note: Endoscopic instruments are designed and manufactured for a specific surgical function. Use of an instrument for a task other than that for which it is intended may result in a damaged or broken instrument.

WARNING: Unless it is stated, do not use *EndoWrist* Instruments on cartilage, bone or hard objects. Doing so may damage the instrument and make it impossible to remove it from the cannula.

EndoWrist ProGrasp Forceps

The *EndoWrist ProGrasp*™ Forceps has been tested and found to be safely used to apply general use bulldog clamps.

The *EndoWrist ProGrasp*™ Forceps has been tested and found to be safely used to manipulate specific laparoscopic ultrasound probes. See the table below for more information on the approved third-party bulldog clamps and ultrasound probes.

Table 2-1 Approved Third-Party Bulldog Clamps and Ultrasound Probes

Manufacturer	Product	PN
Scanlan International	Reliance 25 mm Straight Bulldog Clamp	
	1 clamp	3795-50
	4 clamps and 1 sterilization tray	9999-50
	Reliance 25 mm Curved Bulldog Clamp	
	1 clamp	3795-51
	Reliance 7 mm Straight Bulldog Clamp	
	1 clamp	3795-54
Aloka Ultrasound	Robotic Ultrasound Probe	UST-5550-R
BK Medical	ProArt™ Robotic Transducer	8826

CAUTION: Prior to removing the *ProGrasp* instrument from the cannula, release all approved third-party devices from the *EndoWrist ProGrasp* grips to avoid jamming between the device and cannula, which could make it impossible to remove the *ProGrasp* instrument from the cannula. It is recommended to visualize the *ProGrasp* tip under endoscopic view for removal.

Device Description

EndoWrist Instruments are multiple-use endoscopic instruments to be used in conjunction with the *Intuitive Surgical da Vinci, da Vinci S* and *da Vinci Si* surgical systems. As shown in Figure 2.1, *EndoWrist* Instruments consist of five main components: the Release Levers (A); the Instrument Shaft (B); the Wrist (C); the Tip or End Effector (D); and the Instrument Housing (E).

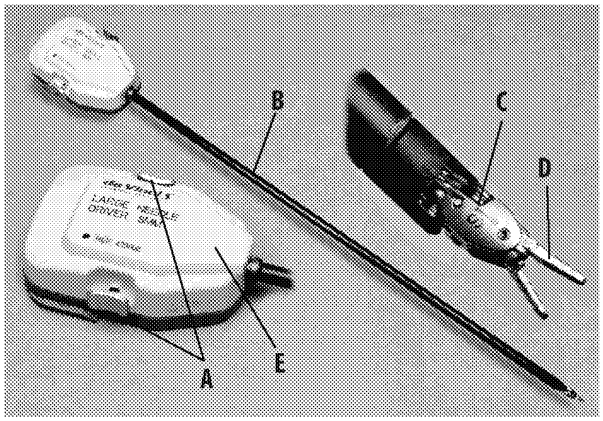


Figure 2.1 EndoWrist instrument

EndoWrist Instruments are available with 5 mm, 8 mm and 12 mm diameter shafts. This section is applicable to non-energized 5 mm and 8 mm *EndoWrist* instruments, which include needle drivers, non-energized graspers, forceps and scissors, and clip appliers. This section also provides general instructions for use for all *EndoWrist* instruments. Energized instruments, or instruments with specialized end effectors, require additional instructions, which are found in the relevant sections of this manual.

Both 5 mm and 8 mm *EndoWrist* instruments can be used with the *da Vinci, da Vinci S* and *da Vinci Si* surgical systems. The *da Vinci* and *da Vinci S* instruments can be differentiated by their length, housing color and graphics.

⚠ **CAUTION: *da Vinci S* instruments are compatible with ONLY the *da Vinci S* and *da Vinci Si* surgical systems.**

⚠ **CAUTION: *da Vinci* instruments are compatible with ONLY the *da Vinci* Surgical System.**

EndoWrist Instruments for *da Vinci*, *da Vinci S*, and *da Vinci Si* Surgical Systems

The *da Vinci* instruments have a light gray housing with the instrument description as shown in Figure 2.2. The *da Vinci* instrument maximum total length is approximately 20.5" (52cm).

Figure 2.2 da Vinci instrument housing—light gray

The *da Vinci S* and *da Vinci Si* instruments have a blue housing with the instrument description as shown in Figure 2.3. The *da Vinci S* instruments are 2" (approximately 5cm) longer than *da Vinci* instruments. They also have the *da Vinci S* logo prominently displayed on the housing.

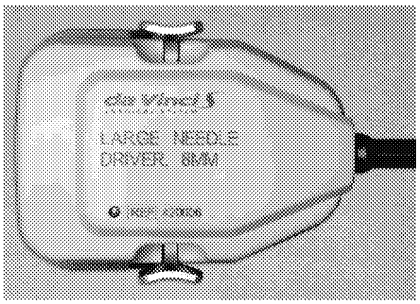


Figure 2.3 da Vinci S and da Vinci Si instrument housing—blue

Flush Ports

The symbol at left indicates flush ports on the instrument housing, as shown below:

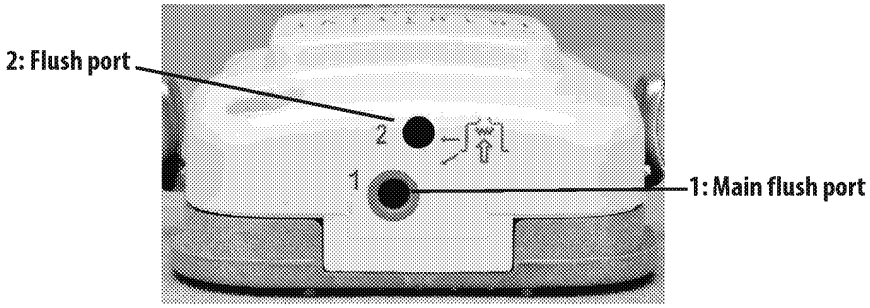


Figure 2.4 Location of flush ports for da Vinci 8 mm EndoWrist instruments

The *da Vinci* 8 mm instruments have two flush ports on the back-end of the instrument housing as shown above. The main flush port is designated by a dark ring and the number 1.

The *da Vinci S* 8 mm instruments have two flush ports on the back-end of the instrument housing as shown in Figure 2.5. The main flush port is designated by a dark ring and the number 1.

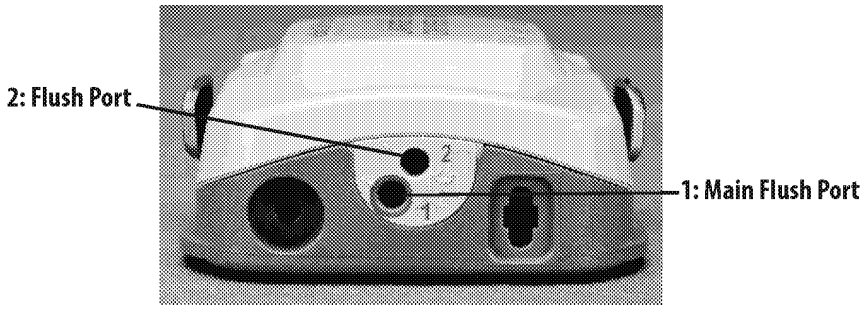


Figure 2.5 Location of flush ports for da Vinci S 8 mm EndoWrist instruments

5 mm instruments have a total of three flush ports. Two flush ports are on the back-end of the instrument housing as shown in Figure 2.4 and Figure 2.5. The third flush port is located where the instrument shaft enters the housing as shown below.

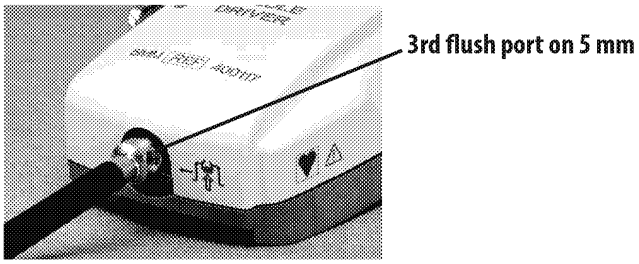


Figure 2.6 Location of third flush port for 5 mm EndoWrist instruments

General Precautions and Warnings

- The grasping force for the *EndoWrist ProGrasp*™ Forceps (PN 400093 and PN 420093) is approximately four times greater than that of the *EndoWrist* Cadiere Forceps (PN 400049 and PN 420049).
- Do not perform grip release on a non-faulted system without first pressing the Emergency Stop button. Failure to observe this warning may result in unintended instrument motion or damage to the grip release mechanism.
- Rotating the grip release tool too far and/or in the incorrect direction can cause unintended instrument motion or damage to the grip release mechanism.
- In case of system failure while the instrument is grasping tissue, the grips can be manually opened by inserting the grip release tool into the grip release hole in the instrument housing and carefully turning. Squeeze the release levers and withdraw the instrument. Use visualization of surgical site when inserting the grip release tool, opening jaws, clearing jaws from tissue, and removing the instrument from the system.
- *EndoWrist* instruments should be handled and operated by trained personnel.
- Handle instruments with care. Avoid mechanical shock or stress that can cause damage to the instruments.
- Use instruments with care. Avoid contact between instruments intraoperatively and do not use one instrument to apply force to another instrument inside the patient.
- Do not deliberately or unintentionally use one instrument to energize other endoscopic instruments. Energizing other endoscopic instruments may cause tissue damage inside or outside the field of view. This damage could occur at points near the tip or at the port site (cannula) of the energized instrument.
- Do not apply prolonged energy to an instrument when it is not in contact with tissue.
- Do not use an instrument to clean debris from another instrument inside the patient. This may result in damage to the instruments or other unintended consequences, such as disconnection of the instrument tip.
- Do not use an instrument to heat another instrument.
- Always have a backup instrument available to complete the surgical procedure in case of instrument failure.
- Clean the instruments immediately after each use. Do not allow debris to dry on or inside the instrument intraoperatively *before* instrument processing. In order to keep the instrument from drying when soiled, keep the instrument in water or an enzymatic bath between the surgical procedure and instrument processing. The instrument may also be flushed through the main flush port with sterile water during use to minimize buildup of internal deposits of bio-material.

2.2 Instructions for Use

Inspection Before Use

Before use, all instruments should be inspected for damage or irregularities. Do not use the instrument if damage or abnormalities are observed. Examples of damage include: broken cables, broken wires, scratches or cracks on the instrument shaft, broken, bent, or gouged instrument tips, cracked or broken pulleys near the instrument tips, cracks or missing pieces on the outer components surrounding the pulleys, loose tip or grips, or broken lever guards (if applicable).

⚠ **CAUTION: Endoscopic instruments are designed and manufactured for a specific surgical function. Use of an instrument for a task other than the instrument's designed use may result in a damaged or broken instrument.**

Intraoperative Use

Intuitive Surgical EndoWrist Instruments should be used only by a physician or medical personnel under the supervision of a physician.

Note: If instruments cannot be manipulated in a precise and controlled manner, of if instrument motion appears to be non-intuitive, contact *Intuitive Surgical* Technical Support immediately. In the US, call 1-800-876-1310, where phones are staffed 24 hours a day, seven days a week. In Europe, call +41.21.821.2020.

Insertion and Removal of Instrument

Always use caution when inserting or removing instruments through the cannula:

- ***Before*** inserting the instrument into the sterile adapter and cannula, make sure the wrist is straight and close the end effectors (if applicable).

⚠ **WARNING: Make sure that the instrument moves smoothly in and out of the cannula.**

⚠ **WARNING: Do not use an instrument to clean debris from another instrument inside the patient. This may result in damage to the instruments or other unintended consequences, such as disconnection of the instrument tip. To clean an instrument intraoperatively, remove the instrument from the system and wipe the instrument tip with moist sterile gauze.**

- Always straighten the instrument wrist under endoscopic visualization ***before*** removal of the instrument through the cannula. To remove the instrument, squeeze the release levers on the housing and withdraw the instrument along the instrument axis.
- When extracting the instrument from the patient, take care not to leave tissue or other debris in the cannula lumen.
- Under normal operating conditions, the cannula and instrument should not be removed simultaneously, as this may damage the surrounding tissues and the instrument. In the event that the instrument cannot be removed from the cannula, under direct vision, try to straighten the instrument wrist; then carefully remove arm with cannula and instrument attached.
- Pull the instrument straight out until it is completely clear of the cannula.

- *EndoWrist* instruments must be used with the appropriate size and type *Intuitive Surgical* cannula. See Chapter 19 Cannulae, Obturators and Accessories for details.
- Any lateral pressure on the instrument during removal may damage, break or disconnect the working tip or bend the shaft.

End of section

3 Electrosurgical Unit (ESU) Settings and Energy Activation Cables

3.1 Introduction

Note: Energy activation cables are non-sterile and do not require sterilization before use.

This section contains instructions for use specific to *da Vinci* energy activation cables, validated electrosurgical units (ESUs) and ESU settings. For information on the operation of approved ESUs, please consult the manual provided with the ESU.

Note: Read Knowing What Applies – Organization of this Manual (page 1-1) to understand what portions of this manual apply to any specific instrument or accessory. If information specific to an instrument or accessory is not supplied in this manual, *Intuitive* supplies it with that instrument or accessory.

Device Description

The energy activation cables are designed to connect a validated electrosurgical unit (ESU) to the *da Vinci*, *da Vinci S*, and *da Vinci Si* Surgical System.

General Precautions and Warnings

WARNING: Do not use any ESU other than those validated for use with the *da Vinci*, *da Vinci S*, or *da Vinci Si* Surgical System.

WARNING: Do not use any energy activation cable or instrument cord other than that indicated as acceptable for the ESU.

WARNING: Do not connect the energy activation cable in any configuration other than that specified in the instructions below.

WARNING: The return electrode must be properly affixed to the patient before the use of electrocautery, to prevent patient or operator injury.

WARNING: Make sure the electrosurgical unit (ESU or generator) is properly functioning before connecting it and using it with the system.

Validated ESUs and Energy Activation Cables

The following ESUs and corresponding energy activation cables are validated for use with the *Intuitive Surgical* Endoscopic Control System:

Table 3-1 Validated ESUs and Energy Activation Cables

	da Vinci Si Energy Activation Cable PN	*da Vinci & da Vinci S* Energy Activation Cable PN	
ESU Model	**Monopolar/Bipolar/Other**	**Monopolar**	**Bipolar**
Covidien Force Triad[a] (formerly ValleyLab)	371715	370193	371498
Covidien Force FX-C (formerly ValleyLab)			
ERBE ICC 350	371871	370447	371499
ERBE VIO 300 D[b]			
ConMed System 5000	371717	371378	371500
Gyrus ACMI G400[c]	371718	NA	370369
Megadyne Mega Power	NA	371484	371483
Ethicon Generator 300 (GEN04) and Hand Piece (HP054)	371870	NA	NA
Ethicon Generator G11[d] (GEN11) and Hand Piece (HP054)			

a. The Covidien Force Triad requires an adapter to connect to a standard four-pin monopolar footswitch. This adapter ships with the generator, and can be ordered from the manufacturer (PN 1017577).
b. The ERBE VIO 300 D requires either a monopolar footswitch adapter (ERBE PN 20140-004) or a bipolar footswitch adapter (ERBE PN 20140-007), which can be ordered from the manufacturer.
c. Minimum recommended software level for Gyrus ACMI G400 is v1.08
d. The da Vinci Si energy activation cable for Ethicon generators (PN 371870) includes an adapter (PN 372600) that allows connection to the GEN11 generator.

Note: Not all *da Vinci* and *da Vinci S* surgical systems are equipped with a bipolar connection and will not be compatible with the above bipolar energy activation cables. Contact your local *Intuitive Surgical* representative to confirm your system's configuration.

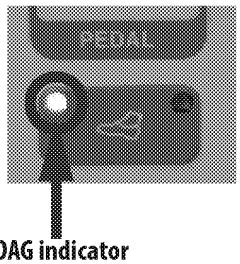
Note: The *da Vinci S* and *Si* instruments have been evaluated for use only with the above ESU generators, and are compatible only with interconnecting cords and ESU generators that are in compliance with IEC 60601-2-2: 1998, IEC 60601-2-2: 2006, or IEC 60601-2-2: 2009.

3.2 Proper Configuration Instructions

WARNING: Ensure that Auto Start is not selected for Bipolar modes. To properly configure the ERBE ICC 350, ERBE VIO 300D, and Covidien Force Triad for use with the surgeon console footswitch, follow the instructions below.

CAUTION: For the ERBE ICC 350, ERBE VIO 300D and Covidien Force Triad, follow the specific configuration instructions provided in this section, to ensure that the desired energy is being activated from the *da Vinci* surgeon console.

ERBE ICC 350



On the ERBE ICC 350, make sure the **COAG** indicator is lit on the PEDAL selector button of the ESU. The COAG indicator is the light on the left side of the PEDAL button, as shown at left and below.

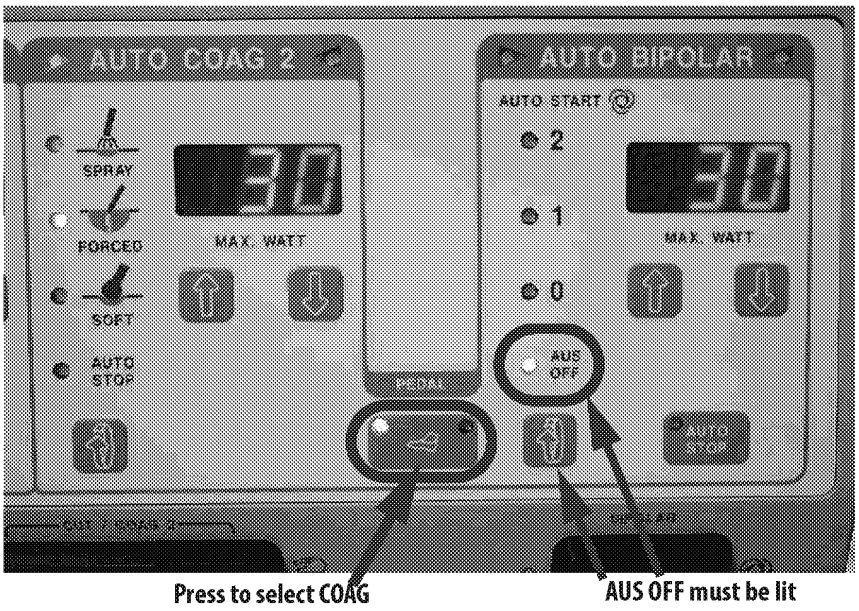


Figure 3.1 Select COAG on the ERBE ICC 350

Ensure that the Auto Start Off indicator is lit (see Figure 3.1). If the Auto Start Off indicator (AUS OFF) is not lit, press the arrow button below it to select it.

If the COAG indicator – the light on the left of the PEDAL button – is not lit, press the PEDAL button to select it, as shown in Figure 3.1.

ERBE VIO 300D

For the ERBE VIO 300D, the correct setting is different for the BIPOLAR and MONOPOLAR receptacles.

Overview

- For a bipolar instrument, make sure the **single footswitch** indicator is lit in the upper, BIPOLAR panel of the ESU, as shown at left and below. If the single footswitch indicator is not lit, go to: To Select Single Footswitch for BIPOLAR, page 3-5.

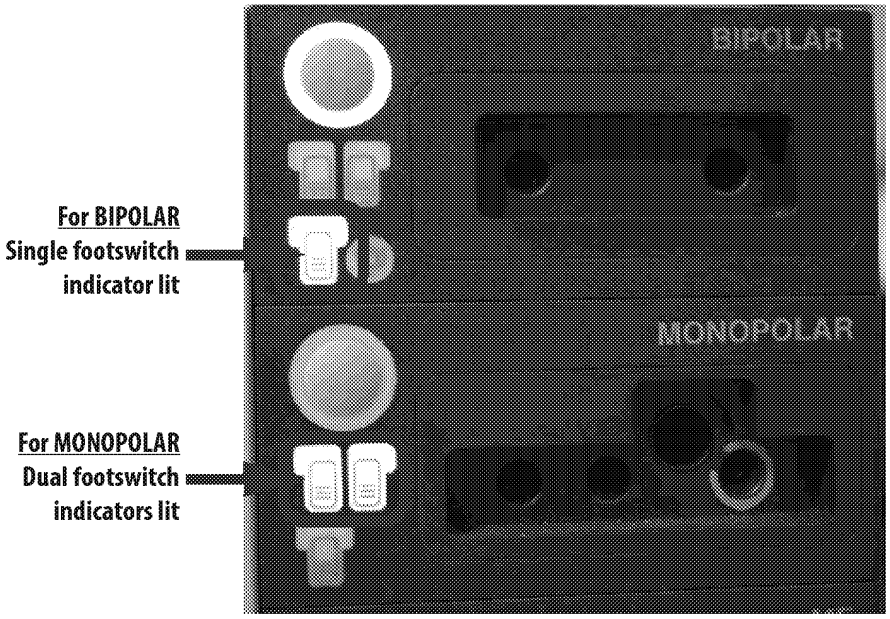


Figure 3.2 ERBE VIO 300D: Select single for BIPOLAR and dual for MONOPOLAR

- For a monopolar instrument, make sure the **dual footswitch** indicators are lit in the lower, MONOPOLAR panel of the ESU, as shown at left and below. If the dual footswitch indicators are not lit, go to: To Select Dual Footswitch for MONOPOLAR, page 3-6.

To Select Single Footswitch for BIPOLAR

1. On the Bipolar receptacle screen, press the upper right soft button to select footswitch setup, as shown:

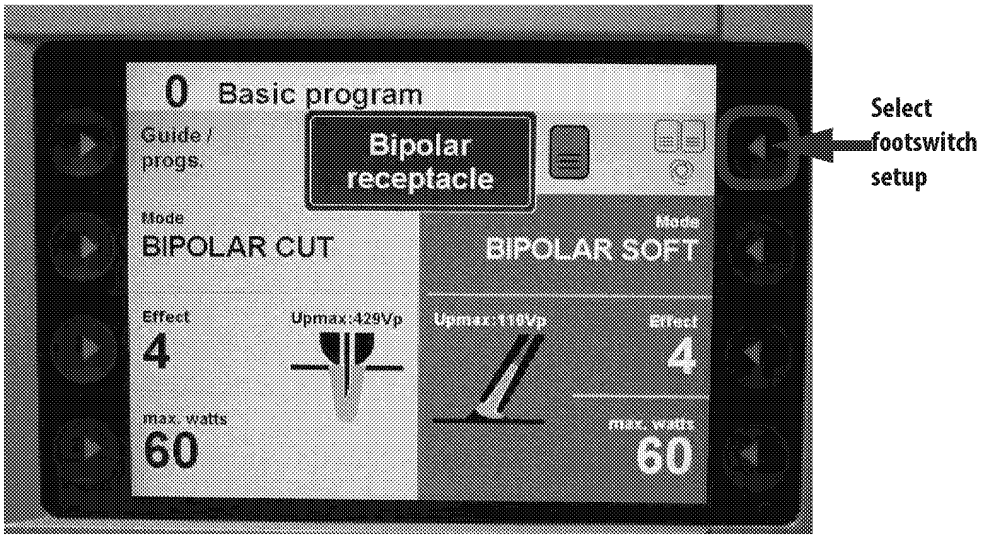


Figure 3.3 Select footswitch setup for Bipolar receptacle

2. On the next screen, which says "**Select activation type:**" for the Bipolar receptacle, select **More**, as shown:

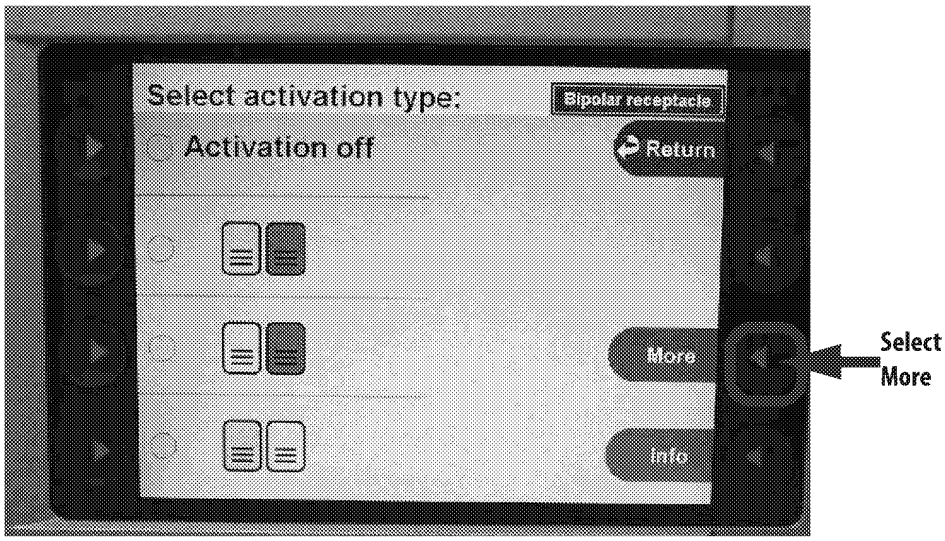


Figure 3.4 Select More

3. On the next screen, select the upper left soft button for **single footswitch**. Do ***not*** select either of the Auto Start modes. When selected, the circle next to the soft button is filled green, as shown:

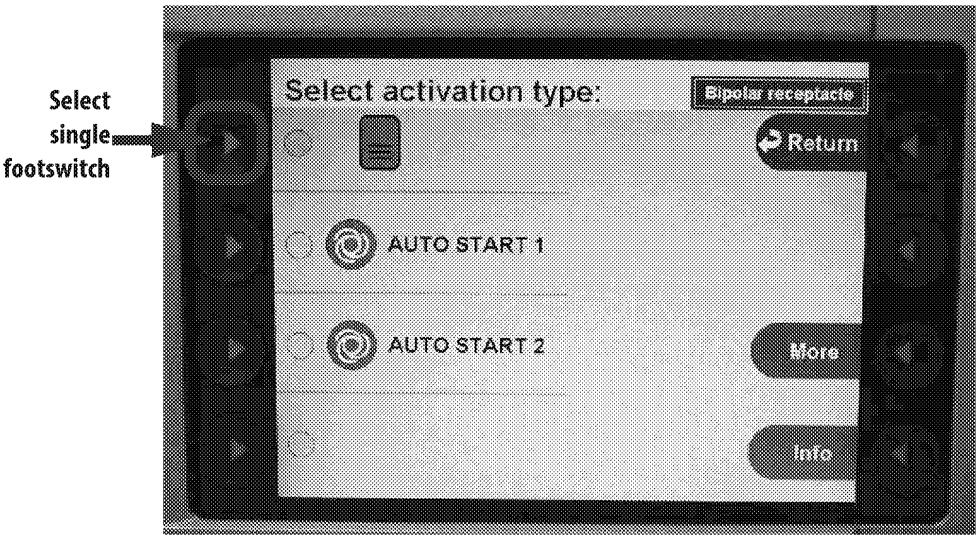


Figure 3.5 Select single footswitch

<u>To Select Dual Footswitch for MONOPOLAR</u>

1. On the Monopolar receptacle screen, press the upper right soft button to select footswitch setup, as shown:

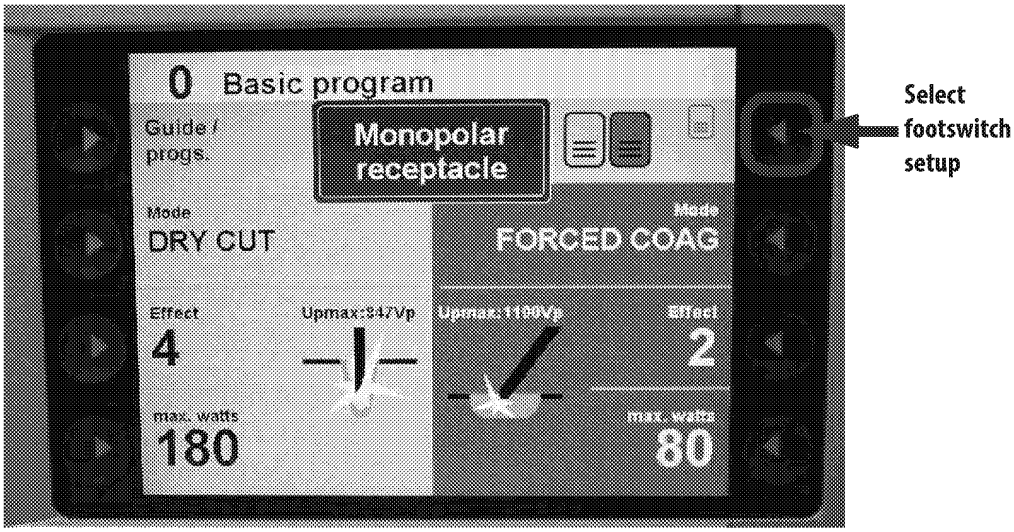


Figure 3.6 Select footswitch setup for Monopolar receptacle

2. On the next screen, which says "**Select activation type:**" for the Monopolar receptacle, select **dual footswitch**, as shown:

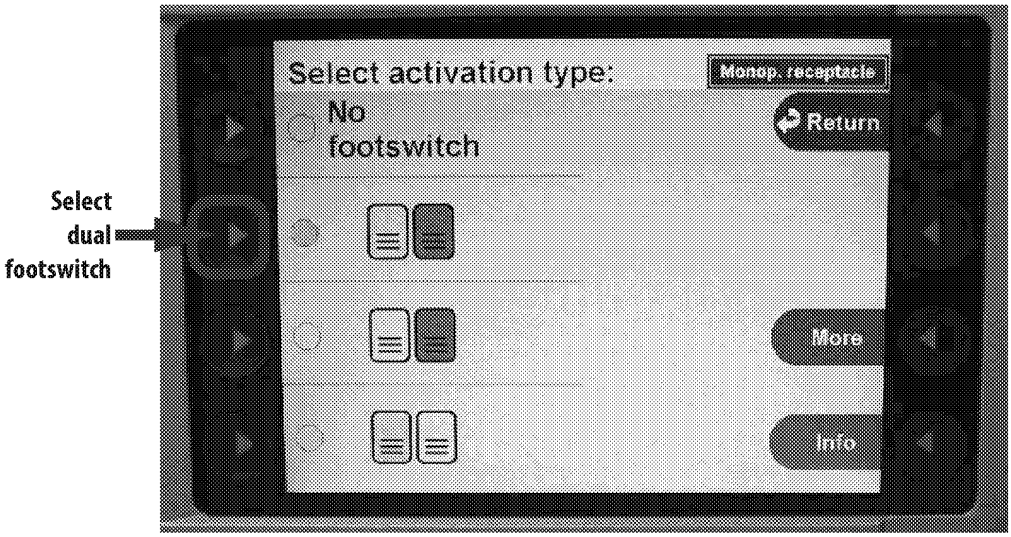


Figure 3.7 Select dual footswitch

Covidien ForceTriad

On the Covidien ForceTriad, make sure that Auto Mode is not selected. When Auto Mode is off (not selected), the screen displays the **Bipolar** tab and Bipolar Mode is selected (Figure 3.8).

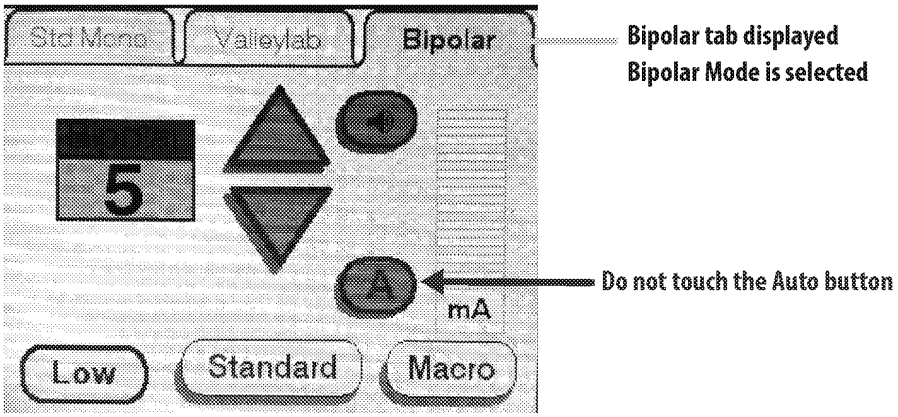


Figure 3.8 Bipolar mode selected

If Auto Mode is selected, the screen displays the **AUTO** tab as shown in Figure 3.9. Touch the **Bipolar** button to return to the **Bipolar** tab and turn off Auto Mode.

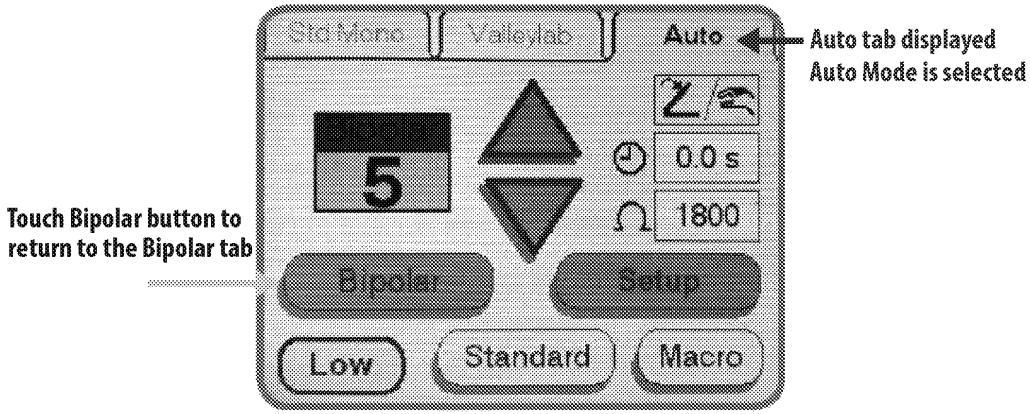


Figure 3.9 Auto Mode selected

Instrument Cord Connections

Table 3-2 Compatible Instrument Cords for Monopolar and Bipolar Energy

Energy Type	Manufacturer	Compatible Instrument Cord
Monopolar	Valleylab 800-722-8772 www.valleylab.com	Reusable Monopolar Cord: Valleylab E2999
Bipolar	Kirwan Surgical Products 888-547-9267 www.ksp.com	Reusable Bipolar Cord: Kirwan 10-5000

⚠ **CAUTION: Connect the ESU to the *EndoWrist* instrument using the appropriate monopolar/bipolar instrument cord. Refer to the ESU's manual for indications and instructions in making this connection. Monopolar cords may only be connected to monopolar receptacles, and bipolar cords to bipolar receptacles.**

Areas outlined in yellow are for monopolar cord connection on each ESU. Areas outlined in red are for bipolar cord connection on each ESU.

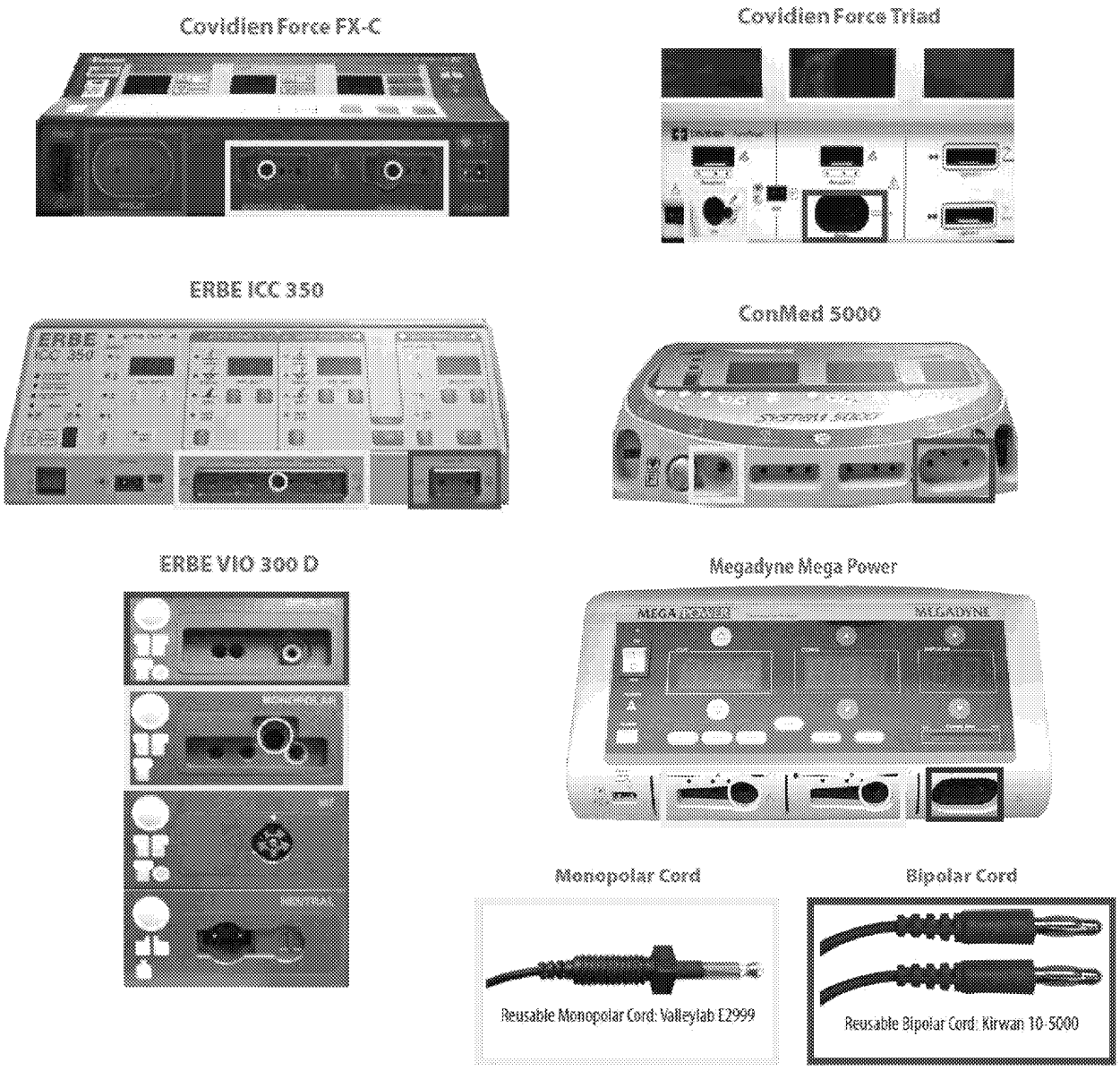


Figure 3.10 Instrument Cord Connections

3.3 Instructions for Use

Electrosurgical Unit (ESU) Preparation

⚠ **CAUTION: Please refer to the individual electrosurgical unit (ESU) manufacturer's user manual for operating instructions.**

1. Prepare the ESU to be used with the instrument as indicated in the ESU's manual.
2. The energy activation cables are shipped with labels on each end of the cable. Connect the cable end labeled **"da Vinci"** to the surgeon console for *da Vinci* and *da Vinci S*, and to the system core for *da Vinci Si*. Connect the other cable end to the ESU.
3. Connect the ESU to the *EndoWrist* instrument using the appropriate monopolar/bipolar instrument cord. Instrument energy cords are properly connected to the instruments when the connector completely covers the exposed pins. Refer to the ESU's manual for indications and instructions in making this connection. For Gyrus ESUs, refer to Chapter 7 PK® Dissecting Forceps.

Note: Ensure that the monopolar instrument cord is plugged into the monopolar receptacle on the ESU and that the bipolar instrument cord is plugged into the bipolar receptacle on the ESU.

4. Turn on the ESU.

Note: The Covidien Force FX-C has multiple monopolar outputs. In this case, there are two receptacles on the front for the monopolar instrument cord and two outlets on the back for the energy activation cable. Ensure that the monopolar instrument cord is plugged into the receptacle corresponding to the outlet that the energy activation cable is plugged into.

Monopolar Cautery Settings

This section covers instructions for electrocautery/electrosurgical use of the *EndoWrist* Permanent Cautery Instruments, the *EndoWrist* 5mm Monopolar Cautery Instrument and the *EndoWrist* Monopolar Curved Scissors.

⚠ **CAUTION: Please refer to the individual ESU manufacturer's user manual for operating instructions.**

Set the ESU to the desired monopolar output. Keep the monopolar Coag settings below the maximum settings in Table 3-3. Set the power as low as possible to achieve adequate hemostasis. Any monopolar Cut mode can be used; however, follow the Recommended use of monopolar Cut mode on page 3-11 below.

⚠ **WARNING: Do not use Monopolar instruments with a bipolar source output as this may cause damage to the instrument and harm to the patient or medical personnel.**

The *EndoWrist* monopolar instruments are intended for electrosurgical applications. They are designed for a maximum peak voltage of 3kV in the "coagulate" and "cut" settings with validated ESUs. Refer to the ESU's manual for maximum peak voltage specifications.

⚠ **WARNING: Do not exceed the 3kV peak limit with monopolar instruments. Doing so may result in electrical arcs and alternate site burns. See Table 3-3 for maximum ESU power settings to stay below this limit for monopolar Coag mode. Do not use any generator or monopolar Coag mode not listed in this table.**

⚠WARNING: Use the lowest power setting possible for the minimum time necessary to achieve the desired effect.

⚠WARNING: Never increase the power settings without first checking both the active electrode and the patient return electrode and their connections. Use the active electrode or forceps only for the minimum time necessary to achieve the desired surgical effect in order to minimize the possibility of burns.

⚠WARNING: Excessive power levels may result in instrument malfunction and possible patient or user injury. Reduce power setting if any of the following effects are observed: excessive arcing, excessive tissue charring, excessive overheating of end effector (e.g., end effector glowing red or emitting a blue plasma cloud).

The approved ESUs, Monopolar Coag Modes and corresponding maximum ESU power settings to stay below the monopolar instrument 3kV limit are as follows. Do not use an unapproved ESU or unlisted monopolar Coag mode.

Table 3-3 Maximum ESU Power Settings to Stay Below the Monopolar Instrument 3kV Limit for Approved ESUs and Monopolar Coag Modes

ESU	Mode	Max Power Setting
Covidien Force Triad	Coag Fulgurate	120 Watts
	Coag Spray	120 Watts
Covidien Force FX-C	Coag Desiccate	120 Watts
	Coag Fulgurate	38 Watts
	Coag Spray	25 Watts
ERBE ICC 350	Coag 2 Forced	120 Watts
	Coag 2 Spray	20 Watts
ERBE VIO 300 D	Soft Coag Effect = 8	200 Watts
	Swift Coag Effect = 8	10 Watts
	Swift Coag Effect = 7	200 Watts
	Forced Coag Effect = 4	120 Watts
	Spray Coag Effect = 2	10 Watts
	Spray Coag Effect = 1	40 Watts
	Precise Coag Effect = 8	50 Watts
ConMed System 5000	Lap: Spray	80 Watts
	Lap: Spray Pulsed	40 Watts
	Lap: Standard	120 Watts
	Lap: Standard Pulsed	60 Watts
	Lap: Pinpoint	120 Watts
Megadyne Mega Power*	Coag Standard	120 Watts
	Coag Spray	120 Watts

*Not approved for use with *da Vinci Si*

Recommended use of monopolar Cut mode

1. Any monopolar Cut mode can be used; however, use the lowest power setting that achieves the desired effect.
2. Apply energy for the minimum time necessary to achieve the desired effect.

3. Ensure that instrument tips are not glowing red and that there is not a blue plasma cloud surrounding the tips. The power setting is too high if these indications are observed.

Bipolar Settings

This section covers instructions for electrocautery/electrosurgical use of the *EndoWrist* Bipolar Instruments. Bipolar instruments are rated for a maximum peak voltage of 500V. Any bipolar Coag mode is acceptable except Forced Coag on the ERBE VIO 300 D generator and Macro on the ConMed System 5000 generator.

⚠ CAUTION: Please refer to the individual ESU manufacturer's Operator's Manuals for operating instructions. Set the ESU to bipolar output. Set the power as low as possible to achieve adequate hemostasis.

⚠ WARNING: Do not use Bipolar instruments with a monopolar source output as this may cause damage to the instrument and harm to the patient or medical personnel.

⚠ WARNING: Do not use bipolar instruments with an electrosurgical generator set in BIPOLAR CUT mode. The use of bipolar instruments with a BIPOLAR CUT mode has not been validated, and may cause damage to the instrument or injury to the patient.

Bipolar Function Check

To verify complete electrical activity before use:

1. Soak a 4"x4" gauze pad with saline.
2. With the instrument slightly open, firmly press the end effectors of the instrument on the gauze pad making sure that both tips touch the pad.
3. Activate the bipolar mode foot pedal connected to the ESU.

⚠ WARNING: Do not touch the end effectors while the foot pedal is activated as this may cause severe electrical injury and/or burn.

Steam generation from the pad or sparking from the end effectors indicates active power and a complete circuit. The instrument is ready for use.

If there is no steam or sparking:

- Verify that the power switch is on and in bipolar mode.
- Ensure ESU is functioning properly.
- Add more saline to the gauze pad.
- Ensure both forceps are touching the saline soaked gauze pad.
- Decrease the amount of pad surface contacting the end effectors.
- Turn power up in small increments.

If steam or sparking is still not evident, do not use the instrument and call *Intuitive Surgical* Customer Service.

Cleaning

Wipe down the energy activation cable periodically using a soft lint free cloth wetted with an anti-microbial solution (isopropyl alcohol, diluted bleach solution, or Cavicide). Do not immerse cable in liquid.

Storage

Store the energy activation cable in a safe location off the floor to prevent damage to the cable.

Disposal

When disposing of these products or any of its components, follow all applicable national and local laws and guidelines.

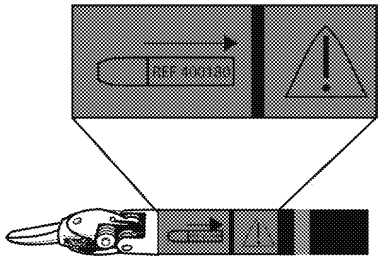
End of section

4 Monopolar Curved Scissors

4.1 Introduction

This section contains instructions for use specific to the *EndoWrist* Monopolar Curved Scissors.

Note: The Monopolar Curved Scissors instrument must ALWAYS be used with Tip Cover Accessory PN 400180, as shown near the tip of the instrument itself.



Note: The Tip Cover Accessory PN 400180 is shipped sterile and is for single use only.

CAUTION: **DO NOT RE-STERILIZE.** **DO NOT RE-USE.**

Reprocessing and/or reuse of products intended for single use only may result in degraded instrument performance or loss of functionality, and in exposure to viral, bacterial, fungal, or prionic pathogens.

CAUTION: **Do not use if package is damaged.**

CAUTION: A breach in the sterile packaging of the device indicates possible contamination. Do not use the device if the packaging is not intact.

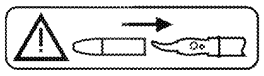
Note: Read Knowing What Applies – Organization of this Manual (page 1-1) to understand what portions of this manual apply to any specific instrument or accessory. If information specific to an instrument or accessory is not supplied in this manual, *Intuitive* supplies it with that instrument or accessory.

Intended Use – Tip Cover Accessory

The Tip Cover Accessory is intended to provide insulation over a section of the *EndoWrist* Monopolar Curved Scissors Instrument so that RF energy is only available at the tip.

General Precautions and Warnings

- **Do not apply energy when scissor tips are not in contact with tissue:** Energy should not be applied to an instrument when it is not in direct contact with tissue (referred to as "air-firing"). Additionally, do not use an electrosurgical instrument to apply cautery to any other instrument.
- **Be aware of critical anatomy in contact with the instrument during energy activation:** While activating monopolar energy, be aware of anatomy that is in contact with the instrument wrist or shaft. The instrument should not be used as a retractor while applying energy.
- **Exercise caution when working with monopolar instruments close to other instruments.** Unintended energy may be delivered from the active monopolar instrument to a second instrument. This could result in burns to tissue in contact with any of the second instrument's metal parts or its cannula. To exercise caution in these scenarios, the monopolar tip should be closer to the tissue than to the second instrument.
- **Survey the surgical field:** During each procedure, surgeons should survey the surgical field, particularly where the distal end of the instrument shaft may have been in contact with tissue. Survey tissue surrounding the main surgical field, including areas "below" or "behind" the cannula and endoscope that are normally outside the field of view.
- **Consider patient condition:** Before using monopolar cautery in a procedure, consider factors that may make a patient's anatomy and tissue more susceptible to injury from the application of cautery (for example, patients that have received radiation therapy prior to surgery).
- The *EndoWrist* Monopolar Curved Scissors Instrument must ALWAYS be used in conjunction with the Tip Cover accessory.



- The *EndoWrist* Monopolar Curved Scissors Instrument must ***always*** be used in conjunction with the appropriately sized *Intuitive Surgical* 8 mm metal cannula.
- The *EndoWrist* Monopolar Curved Scissors Instrument should ***never*** be used with an *Intuitive Surgical* 8 mm metal cannula inserted through a plastic cannula.
- Inspect the Tip Cover Accessory periodically during use. If any damage or tears are observed, replace the Tip Cover Accessory with a new one. Examples of damage include punctures, tears or cuts.
- Do not use another instrument to clean the Tip Cover Accessory.
- If the instrument is flushed intraoperatively, the instrument must be held with the distal tip in an upright position until all fluids are drained from the instrument shaft.

WARNING: Failure to follow these precautions will result in electrical arcs from the wrist and alternate site burns.

WARNING: Do not use this instrument to energize the tips of other instruments. This may damage the end effectors or injure tissue inside or outside the field of view. Tissue damage could occur at points near the tip or at the port site (cannula) of the energized instrument.

- Do not reuse or re-sterilize the Tip Cover Accessory.
- To prevent damage to the Tip Cover Accessory insulation, ***always*** straighten the instrument wrist under endoscopic visualization ***before*** removing the instrument through the cannula.
- During heavy intraoperative cautery application, it may be possible for tissue char to cause the blades to stick together or to reduce cutting performance. Should this occur, remove the instrument and clean the blades with moist gauze or a scrub pad.

Device Description

The *EndoWrist* Monopolar Curved Scissors Instrument is a multiple-use endoscopic instrument utilizing a single-use tip cover accessory, to be used in conjunction with the *Intuitive Surgical* Endoscopic Instrument Control System.

As shown in Figure 4.1, the *EndoWrist* Monopolar Curved Scissors Instrument consists of:

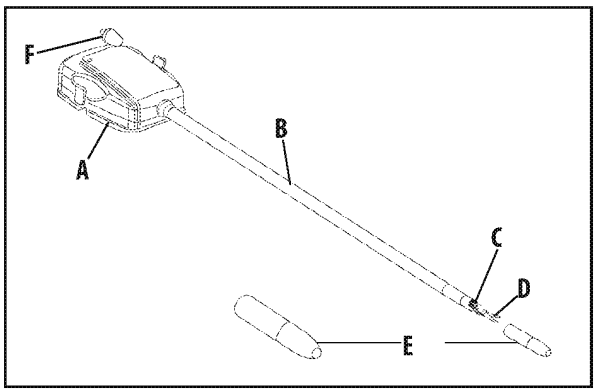
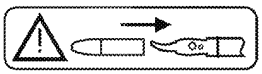


Figure 4.1 EndoWrist Monopolar Curved Scissors Instrument

A. Back end housing with release levers used to remove the instrument from the sterile adapter of the *Intuitive Surgical* Endoscopic Instrument Control System.
B. Insulated shaft
C. Wrist
D. End effector (distal end of Instrument)
E. Tip Cover Accessory PN 400180, shown here, enlarged:



F. Monopolar connector

4.2 Instructions for Use

WARNING: As with any electrosurgical device, it is possible for energy to discharge in an area other than the instrument tip. It is important to exercise caution when using an energized *EndoWrist* Monopolar Curved Scissors Instrument to help avoid unintended contact with tissue adjacent to the area to be cauterized.

Note: During use, if the blades become contaminated by carbonized tissue, remove the instrument and wipe the blades with a piece of moistened, sterile gauze to remove the tissue. Do not use another instrument to clean the blades.

Inspection Before Use

WARNING: If cracks or other flaws are observed on the instrument, do not use the instrument. Examples of damage include nicked, gouged, bent, or loose blades, cracks or scratches on the instrument shaft including the region to be covered by the Tip Cover, or a broken energy cord connector. Contact *Intuitive Surgical* Customer Service.

WARNING: If cracks or flaws are observed on the Tip Cover Accessory, replace the Tip Cover Accessory with a new one and continue to use the instrument. Examples of damage include punctures, tears or cuts.

Tip Cover Accessory Installation – Before Use

The Tip Cover Accessory is provided in a sterile pouch for a single use. Install the Tip Cover Accessory onto the instrument in the sterile field.

1. Close the scissor blades.
2. Straighten the wrist of the instrument. See Figure 4.2 below.
3. Grasping the Tip Cover Accessory with the Installation Tool as shown in Figure 4.2, slide the Tip Cover Accessory onto the distal end of the instrument until it comes to the stop. A twisting motion can be used to ease installation. The distal end of the instrument should be facing away from you during installation.

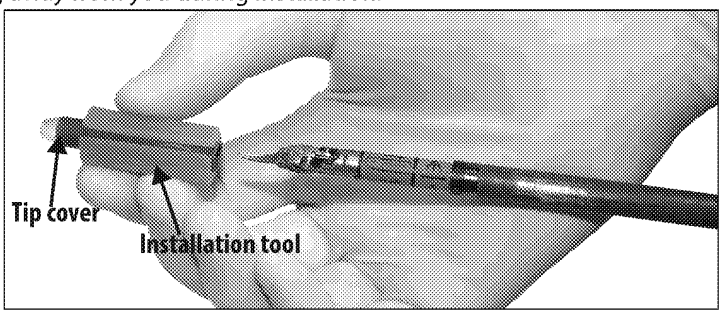


Figure 4.2 Sliding the Tip Cover Accessory onto the instrument

4. Remove the Installation Tool and retain it to aid in removing the Tip Cover Accessory after use. The Tip Cover Accessory is properly installed when the orange surface is completely covered. See Figure 4.3.

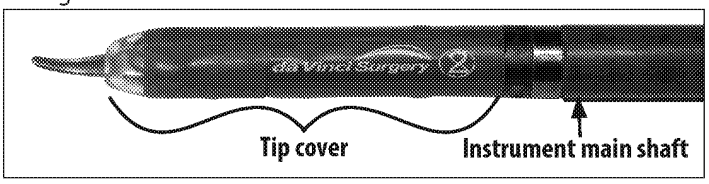


Figure 4.3 Properly installed Tip Cover Accessory in place

The Tip Cover Accessory is ***not*** properly installed if any part of the orange surface is visible, as shown in Figure 4.4.

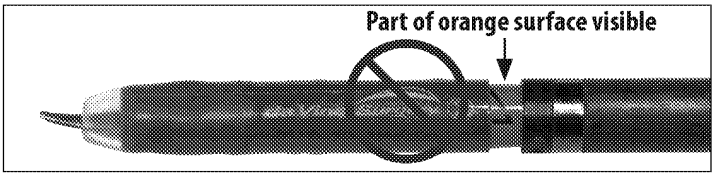


Figure 4.4 Tip Cover Accessory not properly installed

It is also not properly installed if installed beyond the orange surface and over the shaft. This causes a bulge on the shaft and may prevent it fitting through the cannula.

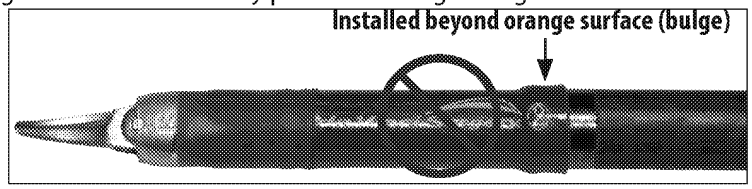


Figure 4.5 Tip Cover over-installed

⚠ WARNING: Failure to install the Tip Cover Accessory properly may result in:

- **Improper scissor opening**
- **Tip Cover Accessory falling off**
- **Electrical arcs and alternate site burns**

Disassembly

After each clinical application, remove the Tip Cover accessory. A twisting motion can be used to ease the removal of the Tip Cover Accessory. The Installation Tool may be reapplied to the Tip Cover Accessory to facilitate removal.

Examine the instrument thoroughly after each use. If any abnormality is detected, do not use the instrument and contact *Intuitive Surgical* Customer Service.

Disposal

Discard the Tip Cover Accessory per institution biohazard protocol.

End of section

5 Permanent Cautery Instruments

5.1 Introduction

This section contains instructions for use specific to *EndoWrist* Permanent Cautery Instruments.

Note: Read Knowing What Applies – Organization of this Manual (page 1-1) to understand what portions of this manual apply to any specific instrument or accessory. If information specific to an instrument or accessory is not supplied in this manual, *Intuitive* supplies it with that instrument or accessory.

Device Description

The *EndoWrist* Permanent Cautery Instruments are multiple use electrosurgical endoscopic instruments. They are to be used in conjunction with the *Intuitive Surgical* Endoscopic Instrument Control System and an external electrosurgical unit (ESU).

As shown in Figure 5.1, the *EndoWrist* Permanent Cautery Instruments consist of the release levers used to remove the instrument from the sterile adapter of the *Intuitive Surgical* Endoscopic Instrument Control System, the instrument shaft and the end effector (for example, hook or spatula).

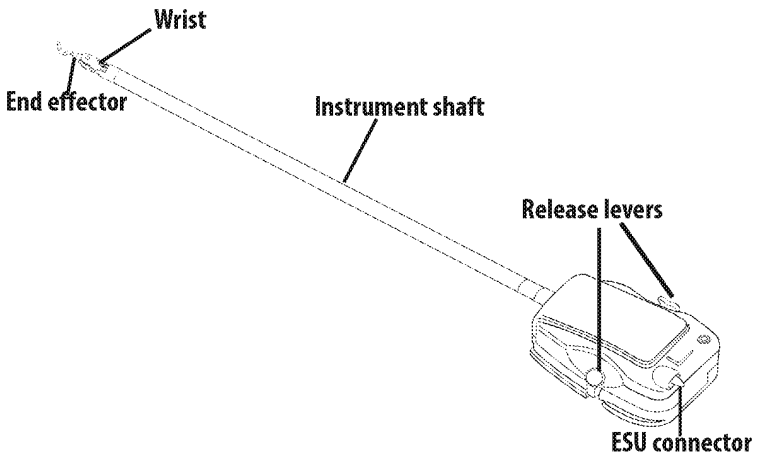


Figure 5.1 EndoWrist Permanent Cautery Instrument

General Precautions and Warnings

WARNING: Always inspect the instrument and instrument tip for abnormalities before use. Do not use the instrument if any abnormalities are observed.

WARNING: Do not use this instrument to energize the tips of other instruments. This may damage the end effectors or injure tissue inside or outside the field of view. Tissue damage could occur at points near the tip or at the port site (cannula) of the energized instrument.

WARNING: Exercise caution when working with monopolar instruments close to other instruments. Unintended energy may be delivered from the active monopolar instrument to a second instrument. This could result in burns to tissue in contact with any of the second instrument's metal parts or its cannula. To exercise caution in these scenarios, the monopolar tip should be closer to the tissue than to the second instrument.

- **Do not apply energy when the instrument tip is not in contact with tissue:** Energy should not be applied to an instrument when it is not in direct contact with tissue (referred to as "air-firing"). Additionally, do not use an electrosurgical instrument to apply cautery to any other instrument.
- **Be aware of critical anatomy in contact with the instrument during energy activation:** While activating monopolar energy, be aware of anatomy that is in contact with the instrument wrist or shaft. The instrument should not be used as a retractor while applying energy.
- **Survey the surgical field:** During each procedure, surgeons should survey the surgical field, particularly where the distal end of the instrument shaft may have been in contact with tissue. Survey tissue surrounding the main surgical field, including areas "below" or "behind" the cannula and endoscope that are normally outside the field of view.
- **Consider patient condition:** Before using monopolar cautery in a procedure, consider factors that may make a patient's anatomy and tissue more susceptible to injury from the application of cautery (for example, patients that have received radiation therapy prior to surgery).
- The Instrument must ***always*** be used in conjunction with the appropriately sized *Intuitive Surgical* 8 mm metal cannula.
- The Instrument should ***never*** be used with an *Intuitive Surgical* 8 mm metal cannula inserted through a plastic cannula.

5.2 Instructions for Use

Inspection Before Use

Before use, examine the entire instrument for damage. If you observe cracks or other damage, or if the tip appears loose, do not use the instrument. Examples of damage include: defects on the hook or spatula tip, damage to the ceramic piece connecting the tip to the wrist, cracked or broken pulleys, cuts on the insulation over the wires, broken energy cord connector, and cracks or scratches on the shaft.

WARNING: As with any electrosurgical device, it is possible for energy to discharge in an area other than the instrument tip. It is important to exercise caution when using an energized *EndoWrist* Permanent Cautery Instrument to help avoid unintended contact with tissue adjacent to the area to be cauterized.

Note: During use, if the tip becomes contaminated by carbonized tissue, remove the instrument and wipe the tip with a piece of moistened, sterile gauze to remove the tissue. Do not use another instrument to clean the tip.

End of section

6 Bipolar Instruments

6.1 Introduction

This section contains instructions for use specific to *EndoWrist* Bipolar Instruments.

Note: Read Knowing What Applies – Organization of this Manual (page 1-1) to understand what portions of this manual apply to any specific instrument or accessory. If information specific to an instrument or accessory is not supplied in this manual, *Intuitive* supplies it with that instrument or accessory.

Device Description

The *EndoWrist* bipolar instruments are multiple use electrosurgical endoscopic instruments with a grasping end effector to be used in conjunction with the *Intuitive Surgical* Endoscopic Instrument Control System and an external electrosurgical unit (ESU).

As shown in Figure 6.1, the *EndoWrist* Bipolar Instruments consist of the ESU connecting section providing the interface between the ESU and the instrument, the release levers used to remove the instrument from the sterile adapter of the *Intuitive Surgical* Endoscopic Instrument Control System, the insertion section of the instrument, and the end effector or tip of the instrument.

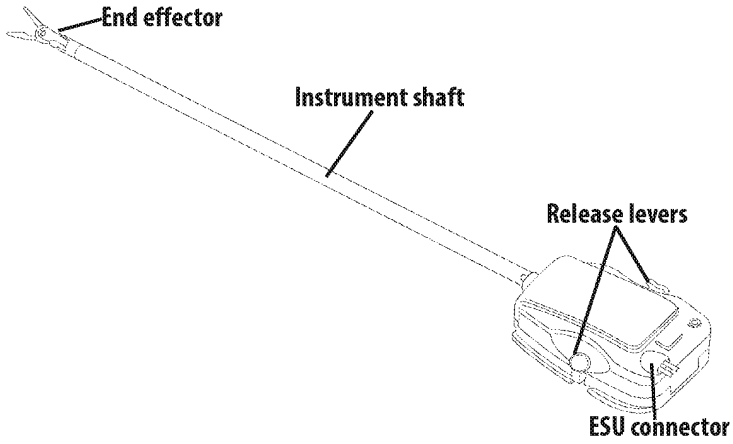


Figure 6.1 EndoWrist Bipolar Instrument

General Precautions and Warnings

WARNING: Do not perform grip release on a non-faulted system without first pressing the Emergency Stop button. Failure to observe this warning may result in unintended instrument motion or damage to the grip release mechanism.

WARNING: Rotating the grip release tool too far and/or in the incorrect direction can cause unintended instrument motion or damage to the grip release mechanism.

WARNING: In case of system failure while these instruments are grasping tissue, the grips can be manually opened by inserting the grip release tool into the grip release hole in the instrument housing and carefully turning. Squeeze the release levers and withdraw the instrument. Use visualization of surgical site when inserting the grip release tool, opening jaws, clearing jaws from tissue, and removing the instrument from the system.

WARNING: Do not use bipolar instruments with an electrosurgical generator set in BIPOLAR CUT mode. The use of bipolar instruments with a BIPOLAR CUT mode has not been validated, and may cause damage to the instrument or injury to the patient.

- Avoid contact with a monopolar instrument that may result in damage to the ESU.
- Discontinue use if any abnormality is experienced during use.

6.2 Instructions for Use

Inspect the instrument for damage prior to use. Examples of damage include bent, broken, or loose grips, cuts on the insulation over the wires, broken energy cord connector, cracked or broken pulleys, and cracks or scratches on the instrument shaft. If any abnormality is observed, discontinue instrument use.

1. Grasp the tissue to be cut or coagulated using the master on the surgeon console. Make sure that the end effectors do not come in contact with non-target tissue.
2. To coagulate the tissue between the end effectors, activate the bipolar ESU by depressing the foot pedal while squeezing the tissue. To coagulate tissue, the two grips of the bipolar instruments must not come in contact with each other. If the tissue is thin and no coagulation occurs, open the grips slightly, press the bipolar foot pedal, and then close the grips to cauterize the tissue. It may also be possible to coagulate very thin structures by directly applying monopolar energy to the tissue.

WARNING: Do not touch the end effectors of the instrument to any staples, clips, or sutures while energized. Damage to the end effectors may occur.

WARNING: Do not use this instrument to energize or heat the tips of other instruments. Damage to the end effectors and injury to the patient may occur.

3. Once coagulating is complete, inspect the surgical area to ensure adequate hemostasis.
4. If the end effectors are contaminated by carbonized tissue, remove the instrument and use a piece of moistened, soft gauze to remove the tissue.

WARNING: Do not attempt to scrape the instrument grips with a sharp object such as a scalpel.

End of section

7 PK® Dissecting Forceps

7.1 Introduction

Note: The PK instrument cords are shipped non-sterile. You must clean and sterilize the cords before use.

This section contains instructions for use specific to the *PK* Dissecting Forceps and PK instrument cords.

Failure to properly follow all instructions, including instructions supplied with the *Intuitive Surgical* System User Manual and the Gyrus ACMI G400 generator manual, may lead to injury and result in improper functioning of the device.

Important: This IFU supplement is designed to provide instructions for use of the *PK* Dissecting Forceps and PK instrument cords in conjunction with the Gyrus ACMI G400 generator. It is not a reference for surgical techniques.

Note: Read Knowing What Applies – Organization of this Manual (page 1-1) to understand what portions of this manual apply to any specific instrument or accessory. If information specific to an instrument or accessory is not supplied in this manual, *Intuitive* supplies it with that instrument or accessory.

Intended Use

The *PK* Dissecting Forceps and PK instrument cords are intended to be used with the *da Vinci, da Vinci S* and *da Vinci Si* Surgical System for endoscopic manipulation of tissue including: grasping, dissecting, approximation, coagulation, retraction and ligation.

WARNING: The *PK* Dissecting Forceps is classified as a BF applied part (symbol shown in Figure 7.1, located on the instrument housing). This instrument is hence not suitable for direct cardiac applications.

Figure 7.1 BF applied part symbol

Contraindications

The *PK* Dissecting Forceps may only be used on soft tissue. Do not use it on cartilage, bone or hard objects. Doing so may damage the instrument or make it impossible to remove from the cannula.

The *PK* Dissecting Forceps is not intended for contraceptive coagulation of the fallopian tube, but may be used to achieve hemostasis following transection of the fallopian tube.

Device Description

The *PK* Dissecting Forceps is a multi-use electrosurgical grasping instrument to be used in conjunction with the *da Vinci*, *da Vinci S* and *da Vinci Si* Surgical System and the Gyrus ACMI G400 generator (Gyrus ACMI generator). This *PK* instrument is rated for a maximum peak voltage of 170V.

The PK instrument cords are designed to connect the *PK* Dissecting Forceps to the corresponding Gyrus ACMI generator as defined in Table 7-1.

As shown in Figure 7.2, the *PK* Dissecting Forceps consists of the Plug Connector providing the interface to the corresponding PK instrument cord as defined in Table 7-1, the Release Levers used to remove the instrument from the sterile adapter of the *da Vinci*, *da Vinci S* and *da Vinci Si* Surgical System, the Instrument Shaft, and the End Effector (or tip) of the instrument.

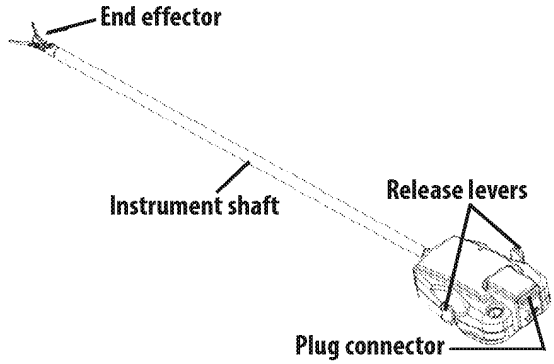


Figure 7.2 EndoWrist PK Dissecting Forceps

General Precautions and Warnings

⚠ WARNING: Do not perform grip release on a non-faulted system without first pressing the Emergency Stop button. Failure to observe this warning may result in unintended instrument motion or damage to the grip release mechanism.

⚠ WARNING: Rotating the grip release tool too far and/or in the incorrect direction can cause unintended instrument motion or damage to the grip release mechanism.

⚠ WARNING: In case of system failure while these instruments are grasping tissue, the grips can be manually opened by inserting the grip release tool into the grip release hole in the instrument housing and carefully turning. Squeeze the release levers and withdraw the instrument. Use visualization of surgical site when inserting the grip release tool, opening jaws, clearing jaws from tissue, and removing the instrument from the system.

⚠ WARNING: Do not connect these instruments to a monopolar source output as this may cause damage to the instrument and harm to the patient or medical personnel.

⚠ WARNING: Avoid contact or close proximity of the *PK* Dissecting Forceps with an active monopolar instrument. This may cause interference with the G400 Workstation resulting in error messages, generator faults or damage to the G400 Workstation. If such damage is suspected, the G400 Workstation should be returned to Gyrus Medical for inspection.

WARNING: Discontinue use if any abnormality is experienced during use.

WARNING: Avoid use of the *PK* Dissecting Forceps in any other configuration other than the generators and cords specified in Table 7-1.

CAUTION: Always have a back-up *PK* Dissecting Forceps and PK instrument cord available to complete the surgical procedure in case of instrument or cord failure.

7.2 Instructions for Use

Inspection Before Use

Before use, the *PK* Dissecting Forceps and PK instrument cords should be inspected for damage or irregularities. Examples of damage include bent, broken, or loose grips, cuts on the insulation over the wires, broken energy cord connector, cracked or broken pulleys, and cracks or scratches on the instrument shaft. If any abnormality is observed, discontinue instrument use. The *PK* Dissecting Forceps is designed and manufactured for a specific surgical function. Use of the instrument for a task other than that for which it is intended may result in a damaged instrument.

Do not use any *PK* Dissecting Forceps or PK instrument cord that is damaged.

Generator Settings

CAUTION: Please refer to the Gyrus ACMI G400 Generator Operator Manual for operating instructions.

1. Prepare the Gyrus ACMI generator to be used with this instrument as indicated in its instruction manual.
2. Connect the Gyrus ACMI generator to the plug connector on the *PK* Dissecting Forceps using the appropriate configuration as shown below:

Table 7-1 PK Instrument Cord Configuration

Gyrus ACMI Generator Type	ISI PK Instrument Cord PN
G400 Generator[a]	400229

a. Minimum recommended software level for Gyrus ACMI G400 is v1.08

Verify that the plug is fully inserted by confirming that the base is flush with the connector on the instrument housing.

WARNING: Do not use any cord other than as specified above while connecting the *PK* Dissecting Forceps to the Gyrus ACMI generator.

WARNING: DO NOT secure the *PK* instrument cord to metallic objects directly or place the PK instrument cord in proximity to other equipment.

WARNING: Ensure that the PK instrument cord does not form a trip hazard in the operating room.

3. Attach the *PK* Dissecting Forceps to the Sterile Adapter of the *da Vinci* and *da Vinci S* Surgical System.
4. Turn on the Gyrus ACMI generator.

5. Ensure that the generator display identifies that the *PK* Dissecting Forceps has been recognized as follows:

Table 7-2 Generator Display

Gyrus ACMI Generator Type	Display Message to Recognize *EndoWrist* PK Dissecting Forceps Instrument
G400 Generator	"da Vinci PK Dissector"

6. The generator is automatically set to VP3-40. The power output can be manually adjusted after the initial setting.

Pre-test Device

To verify complete electrical activity and generator setting ***before*** use:

1. Soak a 4"x4" gauze pad with saline.
2. With the instrument slightly open, firmly press the end effectors of the instrument on the gauze pad making sure that both tips touch the pad.
3. Activate the foot pedal connected to the Gyrus ACMI generator.

⚠ WARNING: Do not touch the end effectors while the foot pedal is activated as this may cause severe electrical injury and/or burn.

- Steam generation from the pad or sparking from the end effectors indicates active power and a complete circuit.
- The Gyrus ACMI generator provides an audible indication when the RF output is active.
- If steam or sparking is observed the instrument is ready for use.

If there is no audible indication provided by the Gyrus ACMI generator:

A. Ensure the footswitch is securely connected, and retest.
B. Ensure the PK instrument cord is securely connected to the Gyrus ACMI generator and the PK Dissector and retest.
C. Ensure the Gyrus ACMI generator displays correctly as indicated in Table 7-2.

If you still do not detect an audible tone, contact Gyrus ACMI Customer Service.

If there is no steam or sparking:

- Verify that the Gyrus ACMI generator power switch is in the on position.
- Ensure Gyrus ACMI generator is functioning properly.
- Add more saline to the gauze pad.
- Ensure both end effectors are touching the saline soaked gauze pad.
- Decrease the amount of pad surface contacting the end effectors.
- Ensure the default power is correct.
- Turn generator power up in small increments.

If steam or sparking is still not evident, *do not* use the device and call *Intuitive Surgical* Customer Service.

Instrument Use

⚠ WARNING: Do not activate the *PK* Dissecting Forceps while the end effectors are within the cannula shaft. Ensure the end effectors have exited the cannula and are in view before depressing the footswitch.

Grasp the tissue to be coagulated by manipulating the master on the surgeon's console. Make sure that the end effectors do not come in contact with non-target tissue.

⚠ WARNING: Ensure that the *EndoWrist* PK Dissecting Forceps end effectors are in the field of view during RF energy activation.

To coagulate the tissue between the end effectors, activate the Gyrus ACMI generator by depressing the foot pedal while squeezing the tissue.

⚠ WARNING: Do not touch the end effectors of the instrument to any staples, clips, or sutures while energized. Damage to the end effectors may occur.

⚠ WARNING: Do not use this instrument to energize or heat the tips of other instruments. Damage to the end effectors and injury to the patient may occur.

Discontinue power application when the tissue has been desiccated. Continued power application may cause the end effectors to stick to the tissue. To alleviate this condition remove end effectors when the tissue is through desiccating and/or flush site with sterile saline in the procedure to keep tissue moist.

Once coagulating is complete, inspect the surgical area to ensure adequate hemostasis.

If the end effectors are contaminated by carbonized tissue, remove the instrument and use a piece of moistened, soft gauze to remove the tissue.

⚠ WARNING: Do not attempt to scrape the end effectors with a sharp object such as a scalpel.

⚠ WARNING: This device is not intended to effect female sterilization.

ⓘ Note: If the Gyrus ACMI G400 generator is placed in standby mode using the Standby/On button on the front of the ESU, the *da Vinci Si* System user interface will still show the PK instrument as being energized, although the PK instrument is not energized and will not fire. The *da Vinci Si* System correctly displays the PK instrument as not energized when its ESU is powered off by disconnecting the AC power or using the power switch on the back of the ESU.

7.3 PK Instrument Cords

The PK instrument cords are reusable for a maximum of twenty (20) reuse cycles. Mark the usage tracker on the cord label after each use.

⚠ WARNING: Do not exceed the recommended number of reuse cycles for the PK instrument cord.

Before first use: Carefully remove the PK instrument cord from the shipping package. Inspect to ensure no damage has occurred during transit.

End of section

8 *Harmonic*® Curved Shears

8.1 Introduction

This section contains instructions for use specific to the *Harmonic* Curved Shears Instrument, including:

- *Harmonic* Curved Shears Instrument, 5 mm
- *Harmonic* Curved Shears Instrument, 8 mm
- *Harmonic* Curved Shears Insert PN 400169

Note: PN 400169 is shipped sterile and is for single use only.

Harmonic is a trademark of Ethicon Endo-Surgery, Inc.

Note: Read Knowing What Applies – Organization of this Manual (page 1-1) to understand what portions of this manual apply to any specific instrument or accessory. If information specific to an instrument or accessory is not supplied in this manual, *Intuitive* supplies it with that instrument or accessory.

Intended Use

The *Harmonic* Curved Shears Instrument is designed to be used in conjunction with both the *da Vinci, da Vinci S* and *da Vinci Si* Endoscopic Instrument Control System and a compatible Ethicon Endo-Surgery Generator and Hand Piece. It is intended for soft tissue incisions when bleeding control and minimal thermal injury are desired.

Contraindications

This instrument may only be used on soft tissue. Do not use it on cartilage, bone or hard objects. Doing so may damage the instrument or make it impossible to remove from the cannula.

The instrument is not intended for contraceptive tubal occlusion.

This instrument should not be used in Cardiac or Central Nervous System applications.

The use of the *Harmonic* Curved Shears Instrument in conjunction with *da Vinci*® Models IS1000 and IS1200 is contraindicated for pediatric patients. In case of Emergency Stop or fault condition, the Instrument Arm may move due to gravity. Should this movement occur when the instrument is in contact with tissue, unintended injury may result.

Device Description

The *Harmonic* Curved Shears Instrument combines a non-sterile reusable instrument housing assembly and a disposable sterile insert with a curved blade and clamp arm.

The *Harmonic* Curved Shears Instruments are designed for use exclusively with a compatible Ethicon Endo-Surgery Generator and Hand Piece. Refer to the list of Compatible Ethicon Endo-Surgery Generators and Hand Pieces on page 8-2. Refer to the Generator Manual before using these instruments.

As shown in Figure 8.1, the *Harmonic* Curved Shears Instrument consists of:

A. A disposable insert (clamp arm and blade) which can be used with both the 5 mm and 8 mm instrument housings.

B. A 5 mm reusable Instrument Housing with release levers and wrench flats.

C. An 8 mm reusable Instrument Housing with release levers and 8 mm shaft.

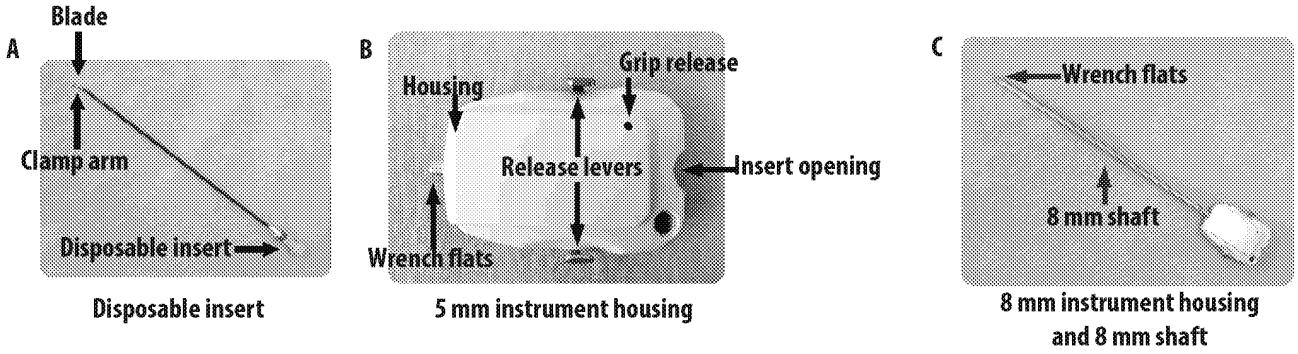


Figure 8.1 Harmonic Curved Shears elements

Note: Both 8 mm and 5 mm *EndoWrist* instruments can be used with the *da Vinci*, *da Vinci S* and *da Vinci Si* surgical systems. The *da Vinci* and *da Vinci S/Si* instruments can be differentiated by their housing color and graphics.

Compatible Ethicon Endo-Surgery Generators and Hand Pieces

Generator	Hand Piece
Generator 300 (Model GEN04)	Model HP054
Generator G11 (Model GEN11)	Model HP054

General Precautions and Warnings

WARNING: In case of Emergency Stop or Fault condition, immediately stabilize the Instrument Arm to prevent unintended movement. This instrument may move due to gravity or other external forces, at a greater rate than other instruments. Remove the instrument immediately to prevent tips from inadvertently contacting tissue.

WARNING: Do not perform grip release on a non-faulted system without first pressing the Emergency Stop button. Failure to observe this warning may result in unintended instrument motion or damage to the grip release mechanism.

WARNING: Rotating the grip release tool too far and/or in the incorrect direction can cause unintended instrument motion or damage to the grip release mechanism.

WARNING: In case of system failure while this instrument is grasping tissue, the grips can be manually opened by inserting the grip release tool into the grip release hole in the instrument housing and carefully turning clockwise. Squeeze the release levers and withdraw the instrument. Use visualization of surgical site when inserting the grip release tool, opening jaws, clearing jaws from tissue, and removing the instrument from the system.

- Minimally invasive procedures should be performed only by persons having adequate training and familiarity with minimally invasive techniques. Consult medical literature relative to techniques, complications, and hazards before performance of any minimally invasive procedure.
- A thorough understanding of the principles and techniques involved in laser, electrosurgical, and ultrasonic procedures is essential to avoid shock and burn hazards to both patient and medical personnel and damage to the device or other medical instruments. Ensure that electrical insulation or grounding is not compromised. Do not immerse instruments in liquid unless the instruments are designed and labeled to be immersed.
- The *Harmonic* Curved Shears Instrument can only be used with a compatible Ethicon Endo-Surgery Generator and Hand Piece.
- Audible high-pitched tones, resonating from the blade or hand piece, is an abnormal condition and an indicator that the blade or hand piece is not operating properly. The tones may be an indicator that the hand piece is beyond its useful life or that the blade has not been attached properly, which may result in abnormally high insert temperatures and user or patient injury. Visually inspect the blade for damage (for example, bent, cracked or broken). If damage exists, do not use the instrument.
- Blood and tissue buildup between the blade and insert may result in abnormally high temperatures at the distal end of the insert. To prevent burn injury, remove any visible tissue buildup at the distal end of the insert by removing the instrument and wiping with moist, sterile gauze.
- As with all energy sources (Electrosurgery, Laser, or Ultrasound), there are concerns about the carcinogenic and infectious potential of the by-products, such as tissue smoke plume and aerosols. Appropriate measures such as protective eyewear, filtration masks, and effective smoke evacuation equipment should be used in both open and laparoscopic procedures.
- Do not attempt to bend, sharpen, or otherwise alter the shape of the blade. Doing so may cause blade failure and user or patient injury.
- To avoid user or patient injury in the event that accidental activation occurs, the instrument blade, clamp arm, and distal end of the insert should not be in contact with the patient, drapes, or flammable materials while not in use. During prolonged activation in tissue, the instrument blade, clamp arm, and distal 7 cm of the insert may become hot. Avoid unintended contact with tissue, drapes, surgical gowns, or other unintended sites at all times.
- Avoid contact with any and all metal or plastic instruments or objects when the instrument is activated. Contact with staples, clips, or other instruments while the instrument is activated may result in cracked or broken blades, which may be identified by a generator solid tone or an instrument error.
- Care should be taken not to apply pressure between the blade and clamp arm without having tissue between them. This can result in possible damage to the instrument. Both conditions may cause a system failure signaled by a continuous beep when either of the foot pedals is depressed.

- The entire exposed blade tip is active and will cut/coagulate tissue when the blade is activated. Be careful to avoid inadvertent contact between all exposed blade surfaces and surrounding tissue when using the *Harmonic* Curved Shears Instrument.
- After removing the instrument, examine the tissue for hemostasis. If hemostasis is not present, appropriate techniques should be used to achieve hemostasis.
- When using *Harmonic* Curved Shears Instruments on solid organs, use caution. Due to the device's limited ability to grasp large portions of solid organs and occlude vascular structures of this nature, hemostasis may not be predictable and may require adjunct measures for coagulation.
- Products manufactured or distributed by companies not authorized by Intuitive Surgical, Inc. may not be compatible with the *Harmonic* Curved Shears Instrument and the *da Vinci* Surgical System. Use of such products may lead to unanticipated results and possible injury to the user or patient.

Note: Do not introduce or withdraw the instrument insert with the jaws open through the cannula as this may damage the instrument.

Note: In case of system failure, ensure the availability of appropriate back up equipment relative to the specific procedure.

- Instruments or devices which come into contact with bodily fluids may require special disposal handling to prevent biological contamination.
- Dispose of all opened disposable instrument parts whether used or unused. Do not re-sterilize the instrument insert. Resterilization may compromise the integrity of this product, which may result in unintended injury.

8.2 Instructions for Use

Verify compatibility of all instruments and accessories before using the instrument (refer to General Precautions and Warnings).

The reusable housing must be cleaned and sterilized per instructions before each use.

Inspection Before Use

Examine the instrument for damage before use. Examples of damage include: a bent, cracked, or broken blade on the insert; a bent, cracked, or broken clamp arm on insert; a damaged or loose pad on the clamp arm; cracks or flaws on the shaft of the insert; cracks or flaws on the reusable instrument housing.

CAUTION: If cracks or other flaws are observed, do not use the instrument.

Attaching the Ethicon Endo-Surgery Hand Piece to the Disposable Insert

The hand piece is attached to the disposable insert using a torque wrench supplied with the hand piece, as shown below.

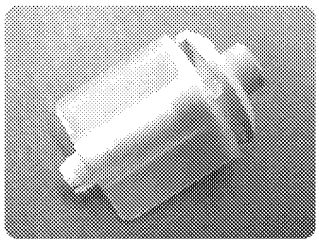


Figure 8.2 Torque wrench

1. Attach the hand piece to the insert by rotating the insert in a clockwise direction until the connection is finger tight. See Figure 8.3

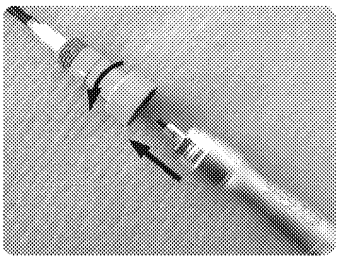


Figure 8.3 Attaching the insert to the hand piece

2. Slide the torque wrench over the end effector and onto the wrench flats. Hold the hand piece and turn the wrench in a clockwise direction until you hear one click. See Figure 8.4

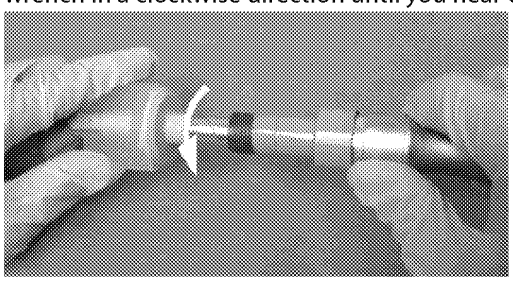


Figure 8.4 Using the torque wrench to secure the insert

Attaching the Hand Piece/Insert Assembly to the Housing

1. Slide the insert with jaws closed through the opening in the housing. See Figure 8.5

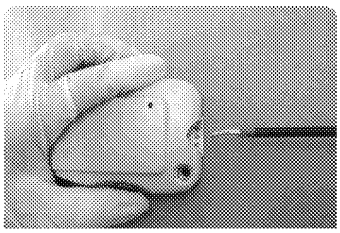


Figure 8.5 Inserting the jaws

2. Slide the torque wrench over the end effector onto the wrench flats of the housing.

3. Hold the hand piece (not the housing) in one hand and the torque wrench in the other. While pushing the wrench and hand piece together, turn the wrench in a clockwise direction until you hear one click. (It will take approximately two turns of the wrench.) See Figure 8.6.

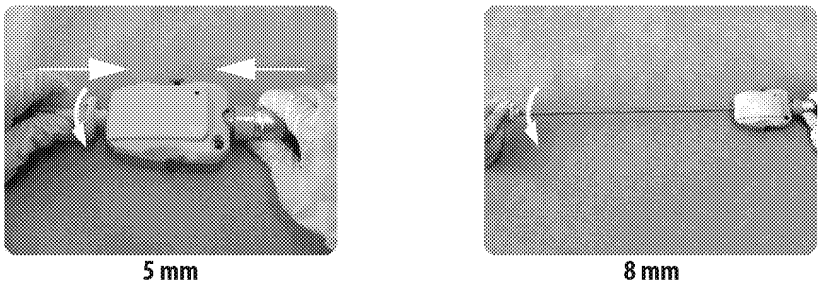


Figure 8.6 Attaching the assembly to the 5 mm (left) and 8 mm (right) reusable housing

Note: If you do not hear a click after several turns of the wrench, pull the insert partially out of the housing, rotate the insert 180 degrees and re-engage into the housing.

4. Slide the wrench down the insert and remove it completely.
5. Confirm that the insert is securely attached to the housing by trying to slide the insert out while holding the housing.

Note: When assembled, the jaws of the instrument close automatically. The jaws must be open during the generator self-test. A generator fault may occur if the jaws are in the closed position during the generator self-test.

6. Open the jaws (clamp arm and blade) by pushing the Insert (not the hand piece) toward the housing. See Figure 8.7

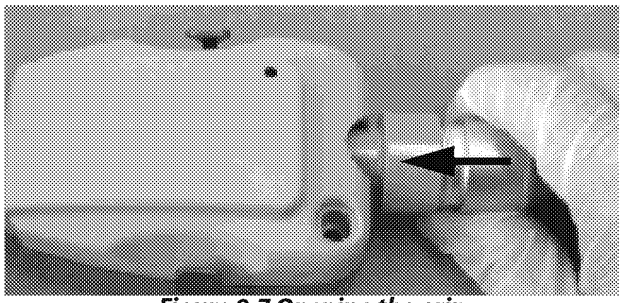


Figure 8.7 Opening the grip

7. Plug the end of the cord for the hand piece into the generator and turn the generator power on.

Note: Do not turn the generator power on before the hand piece and instrument are connected to the generator.

CAUTION: The *Harmonic* Curved Shears Instrument can only be used with a compatible Ethicon Endo-Surgery Generator and Hand Piece. Refer to the list of Compatible Ethicon Endo-Surgery Generators and Hand Pieces on page 8-2. It is not compatible with the ULTRACISION Generator (GEN01/GEN32).

8. Select the desired minimum (MIN) power level using the **INCREASE** and **DECREASE** buttons on the generator.

Note: The recommended minimum (MIN) starting power level is Level 2. For greater tissue cutting speed use a higher generator power level, and for greater coagulation use a lower generator power level. The amount of energy delivered to the tissue and resultant tissue effects are a function of many factors, including the power level selected, blade characteristics, grip force, tissue tension, tissue type, pathology, and surgical technique.

9. For optimal performance, clean the instrument blade, clamp arm and distal end of the insert throughout the procedure by activating the end of the insert in saline.

Note: Do not touch the instrument to metal while activated.

Note: Do not clean the blade tip with abrasives. It can be wiped with a moist gauze sponge to remove tissue, if necessary.

10. If tissue is visible in the clamp arm, use hemostats to remove residue with the generator in Standby mode.
11. The blade is ultrasonically energized when either Ethicon Generator footswitch pedal is depressed.

Note: Scratches on the blade may lead to premature blade failure.

- **Avoid accidental contact with other instruments during use.**
- **Do not use any means other than the blade wrench to attach or detach the instrument from the hand piece.**

Intraoperative Use

Use the *Harmonic* Curved Shears Instrument for dissection, grasping, coagulation, and cutting between the blade and clamp arm. Use the outside edge of the blade for backcutting.

Note: Keep the clamp arm open when backcutting, or while the blade is active without tissue between the blade and tissue pad, to avoid damage to the tissue pad.

Disassembly

1. After each clinical application, Turn the generator OFF at the power switch or enter Standby mode.

2. Slide the torque wrench over the end effector of the insert and onto the wrench flats of the housing. While holding the hand piece (do not grasp the housing) turn the wrench in a counterclockwise direction for several turns until the housing is free to slide off the insert.

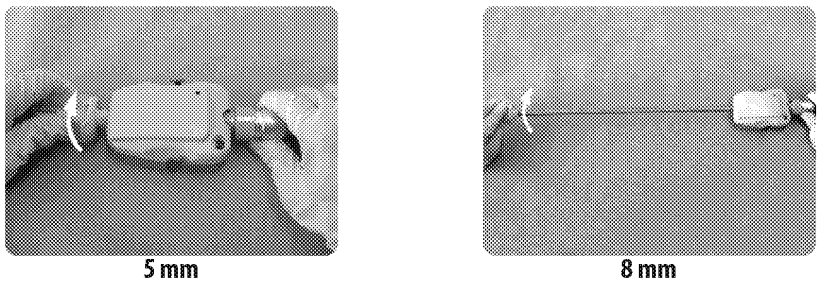


Figure 8.8 Removing the insert from the housing

Note: Take care to avoid injury from the blade tip while sliding the torque wrench onto or off of the insert.

3. Remove the wrench by sliding it back over the insert. Save the wrench for future use.
4. While grasping the hand piece, slide the insert out of the housing.
5. Slide the torque wrench over the end effector and onto the wrench flats on the insert. Holding the hand piece, turn the wrench in a counterclockwise direction.

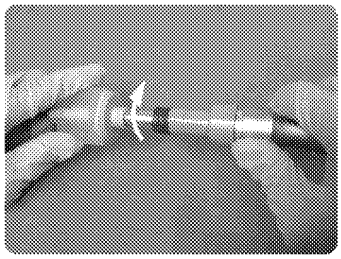


Figure 8.9 Loosening the insert

6. When the insert is loosened, remove the wrench and manually rotate the insert until it separates from the hand piece. See Figure 8.10

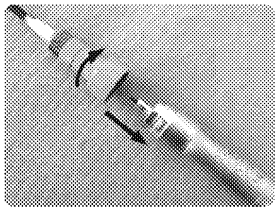


Figure 8.10 Removing the insert from the hand piece

7. Dispose of the insert in an appropriate container per institution biohazard protocol.

When disposing of this product or any of its components, follow all applicable national and local laws and guidelines.

End of section

9 *Harmonic ACE®* Curved Shears

9.1 Introduction

This section contains instructions for use specific to the *Harmonic ACE* Curved Shears Instrument, including:

- *Harmonic ACE* Curved Shears Instrument, 5 mm
- *Harmonic ACE* Curved Shears Instrument, 8 mm
- *Harmonic ACE* Curved Shears Disposable Insert PN 400272

Note: PN 400272 is shipped sterile and is for single use only.

Harmonic ACE is a trademark of Ethicon Endo-Surgery, Inc.

Note: Read Knowing What Applies – Organization of this Manual (page 1-1) to understand what portions of this manual apply to any specific instrument or accessory. Failure to properly follow all instructions, including instructions supplied with *Intuitive Surgical* system user manuals, may lead to injury and result in improper functioning of the device.

Intended Use

The *da Vinci Harmonic ACE* Curved Shears is intended for soft tissue incisions when bleeding control and minimal thermal injury are desired. It is designed to be used in conjunction with the *da Vinci* Surgical Systems (Models IS1200, IS2000 and IS3000) and a compatible Ethicon Endo-Surgery Generator and Hand Piece.

Contraindications

This instrument may only be used on soft tissue. Do not use it on cartilage, bone or hard objects. Doing so may damage the device or make it impossible to remove from the cannula.

The instrument is not intended for contraceptive tubal occlusion.

This instrument should not be used in cardiac or central nervous system applications.

The use of the *da Vinci Harmonic ACE* Curved Shears in conjunction with *da Vinci®* Models IS1000 and IS1200 is contraindicated for pediatric patients. In case of an Emergency Stop or Fault condition, the instrument arm may move due to gravity. Should this movement occur when the device is in contact with tissue, unintended injury may result.

Device Description

The *da Vinci Harmonic ACE* Curved Shears combines a non-sterile reusable instrument housing assembly and a disposable sterile insert with a curved blade and clamp arm.

Note: The *da Vinci Harmonic ACE* Curved Shears are designed for use exclusively with a compatible Generator and Hand Piece. Refer to the list of Compatible Ethicon Endo-Surgery Generators and Hand Pieces on page 9-3. Refer to the Generator Manual before using these instruments.

As shown in Figure 9.1, the *da Vinci Harmonic ACE* Curved Shears consists of:

A. A disposable insert (clamp arm and blade) which can be used with both the 5 mm and 8 mm instrument housings.

B. A 5 mm reusable instrument housing with release levers and wrench flats.

C. An 8 mm reusable instrument housing with release levers and 8 mm shaft.

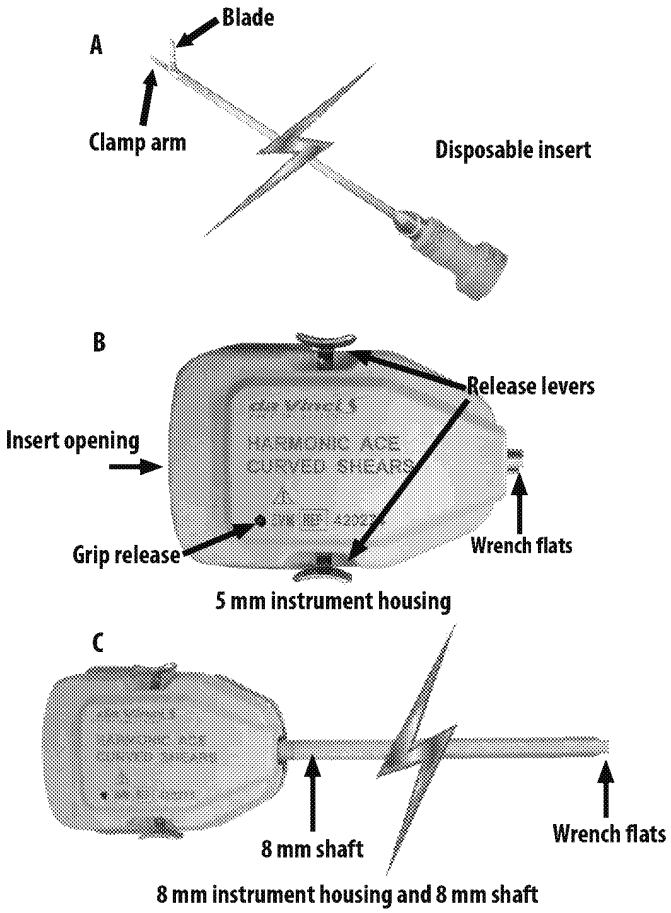


Figure 9.1 Harmonic ACE Curved Shears elements

The *da Vinci Harmonic ACE* Curved Shears allow for the coagulation of vessels up to and including 5 mm in diameter.

Both 8 mm and 5 mm curved shears can be used with the *da Vinci* and *da Vinci S/Si* surgical systems. The *da Vinci* and *da Vinci S/Si* instruments can be differentiated by their housing color and graphics.

WARNING: *da Vinci* instruments are compatible with ONLY the *da Vinci* Surgical System. *da Vinci S* instruments are compatible with ONLY the *da Vinci S* and *da Vinci Si* surgical systems.

Instruments for the *da Vinci* Surgical Systems

The *da Vinci* instruments have a light gray housing with the word "*EndoWrist*" prominently displayed on the housing.

The *da Vinci S/Si* instruments have a blue housing with "*da Vinci S*" prominently displayed on the housing.

Compatible Ethicon Endo-Surgery Generators and Hand Pieces

Generator	Hand Piece
Generator 300 (Model GEN04)	Model HP054
Generator G11 (Model GEN11)	Model HP054

General Precautions and Warnings

⚠ WARNING: On IS1000 and IS1200 (standard *da Vinci)* systems, in case of an Emergency Stop or Fault condition, immediately stabilize the instrument arm to prevent unintended movement. This instrument may move due to gravity or other external forces, at a greater rate than other instruments. Remove the instrument immediately to prevent tips from inadvertently contacting tissue.

⚠ WARNING: Do not perform grip release on a non-faulted system without first pressing the Emergency Stop button. Failure to observe this warning may result in unintended instrument motion or damage to the grip release mechanism.

⚠ WARNING: Rotating the grip release tool too far and/or in the incorrect direction can cause unintended instrument motion or damage to the grip release mechanism.

⚠ WARNING: In case of system failure while this instrument is grasping tissue, the grips can be manually opened by inserting the grip release tool into the grip release hole in the instrument housing and carefully turning clockwise. Squeeze the release levers and withdraw the instrument. Use visualization of surgical site when inserting the grip release tool opening jaws, clearing jaws from tissue, and removing the instrument from the system.

- **Minimally invasive procedures should be performed only by persons having adequate training and familiarity with minimally invasive techniques. Consult medical literature relative to techniques, complications, and hazards before performance of any minimally invasive procedure.**
- **A thorough understanding of the principles and techniques involved in laser, electrosurgical, and ultrasonic procedures is essential to avoid shock and burn hazards to both patient and medical personnel and damage to the device or other medical instruments. Ensure that electrical insulation or grounding is not compromised. Do not immerse instruments in liquid unless the instruments are designed and labeled to be immersed.**
- **The *da Vinci Harmonic ACE* Curved Shears can only be used with a compatible Ethicon Endo-Surgery Generator and Hand Piece.**

- Audible high-pitched tones, resonating from the blade or hand piece, are an abnormal condition and an indicator that the blade or hand piece is not operating properly. The tones may be an indicator that the hand piece is beyond its useful life or that the blade has not been attached properly, which may result in abnormally high insert temperatures and user or patient injury. Visually inspect the blade for damage (for example, bent, cracked or broken). If damage exists, do not use the instrument.
- Blood and tissue buildup between the blade and insert may result in abnormally high temperatures at the distal end of the insert. To prevent burn injury, remove any visible tissue buildup at the distal end of the insert by removing the instrument and wiping with moist gauze.
- As with all energy sources (Electrosurgery, Laser, or Ultrasound), there are concerns about the carcinogenic and infectious potential of the by-products, such as tissue smoke plume and aerosols. Appropriate measures such as protective eyewear, filtration masks, and effective smoke evacuation equipment should be used in both open and laparoscopic procedures.
- Do not attempt to bend, sharpen, or otherwise alter the shape of the blade. Doing so may cause blade failure and user or patient injury.
- To avoid user or patient injury in the event that accidental activation occurs, the instrument blade, clamp arm, and distal end of the insert should not be in contact with the patient, drapes, or flammable materials while not in use. During prolonged activation in tissue, the instrument blade, clamp arm, and distal 7 cm of the insert may become hot. Avoid unintended contact with tissue, drapes, surgical gowns, or other unintended sites at all times.
- Avoid contact with any and all metal or plastic instruments or objects when the device is activated. Contact with staples, clips, or other instruments while the device is activated may result in cracked or broken blades, which may be identified by a generator solid tone or an instrument error.
- Care should be taken not to apply pressure between the blade and clamp arm without having tissue between them. This can result in possible damage to the instrument. Both conditions may cause a system failure signaled by a continuous beep when either of the foot pedals is depressed.
- The entire exposed blade tip is active and will cut/coagulate tissue when the blade is activated. Very high temperatures (greater than 200 degrees C) can be generated. Be careful to avoid inadvertent contact between all exposed blade surfaces and surrounding tissue when using the *da Vinci Harmonic ACE* Curved Shears.
- After removing the device, examine the tissue for hemostasis. If hemostasis is not present, appropriate techniques should be used to achieve hemostasis.
- When using *da Vinci Harmonic ACE* Curved Shears on solid organs, use caution. Due to the device's limited ability to grasp large portions of solid organs and occlude vascular structures of this nature, hemostasis may not be predictable and may require adjunct measures for coagulation.

- Products manufactured or distributed by companies not authorized by Intuitive Surgical, Inc. may not be compatible with the *da Vinci Harmonic ACE* Curved Shears and the da Vinci Surgical System. Use of such products may lead to unanticipated results and possible injury to the user or patient.

Note: Do not introduce or withdraw the instrument insert with the jaws open through the trocar sleeve as this may damage the instrument.

Note: In case of system failure, ensure the availability of appropriate back up equipment relative to the specific procedure.

- Instruments or devices which come into contact with bodily fluids may require special disposal handling to prevent biological contamination.
- Dispose of all opened disposable instrument parts whether used or unused. Do not re-sterilize the instrument insert. Resterilization may compromise the integrity of this product, which may result in unintended injury.

9.2 Instructions for Use

Verify compatibility of all instruments and accessories before using the instrument (refer to General Precautions and Warnings).

The reusable housing must be cleaned and sterilized per instructions before each use.

WARNING: Read all instructions carefully. Failure to properly follow instructions may lead to electrical or ultrasonic injury and cause improper functioning of the device.

Inspection Before Use

Examine the instrument for damage before use. Examples of damage include: a bent, cracked, or broken blade on the insert; a bent, cracked, or broken clamp arm on insert; a damaged or loose pad on the clamp arm; cracks or flaws on the shaft of the insert; cracks or flaws on the reusable instrument housing. Inspect packaging for tears and do not use if the package is damaged.

CAUTION: If cracks or other flaws are observed, do not use the instrument.

CAUTION:  **Do not use if package is damaged.**

Attaching the Ethicon Endo-Surgery Hand Piece to the Disposable Insert

The hand piece (PN HP054) is attached to the disposable insert using the torque wrench (PN TWGRAY) supplied with the disposable insert.

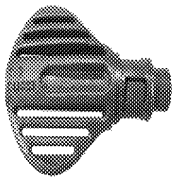


Figure 9.2 Torque wrench (PN TWGRAY)

1. Attach the hand piece to the insert by rotating the insert in a clockwise direction until the connection is finger tight. See Figure 9.3

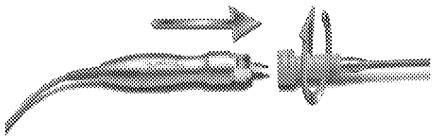


Figure 9.3 Attaching the insert to the hand piece

2. Slide the torque wrench over the closed jaws and onto the wrench flats. Hold only the hand piece and turn the wrench clockwise to tighten until you hear one "click," which indicates sufficient torque has been applied to secure the blade. See Figure 9.4

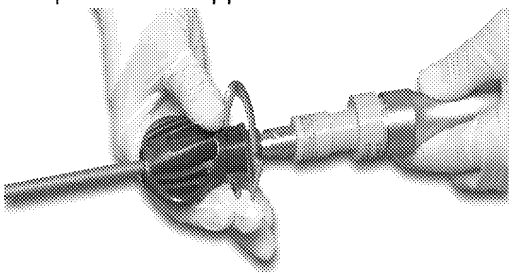


Figure 9.4 Using the torque wrench to secure the insert

Attaching the Hand Piece/Insert Assembly to the Housing

1. Remove the torque wrench. Slide the insert with jaws closed through the opening in the housing. See Figure 9.5

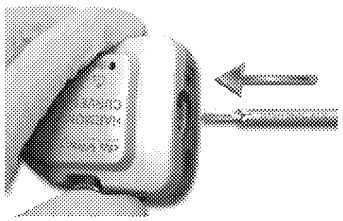


Figure 9.5 Inserting the grips, or jaws

2. The next step varies slightly for the 8 mm and 5 mm instruments, as explained below. Follow these instructions closely to make sure the insert engages inside the housing.

For 8 mm instrument:

A. ***While holding the instrument housing and hand piece together***, hand tighten the gray shaft until finger-tight. See Figure 9.6

8 mm instrument (a)

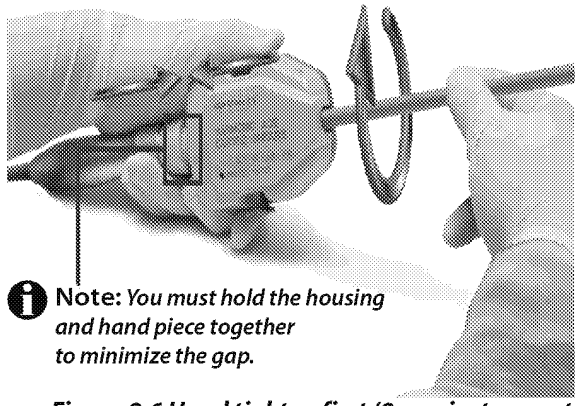


Figure 9.6 Hand tighten first (8 mm instrument only)

B. Slide the torque wrench over the jaws onto the wrench flats and turn the wrench in a clockwise direction until you hear one "click." See Figure 9.7

8 mm instrument (b)

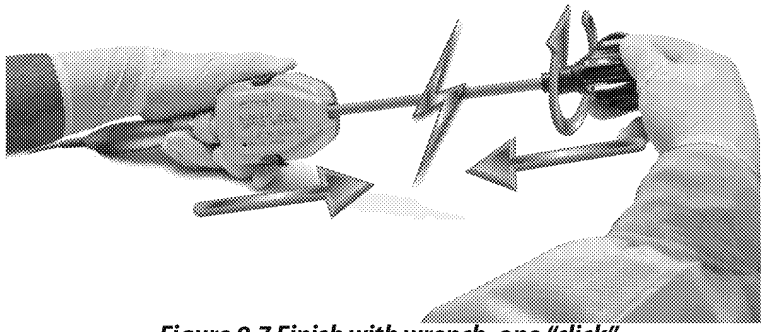


Figure 9.7 Finish with wrench, one "click"

For 5 mm instrument:

A. Slide the torque wrench over the jaws onto the wrench flats. ***While firmly pushing the wrench and hand piece together,*** turn the wrench in a clockwise direction until you hear one "click." (It will take approximately two turns of the wrench.) See Figure 9.8

5 mm instrument (a)

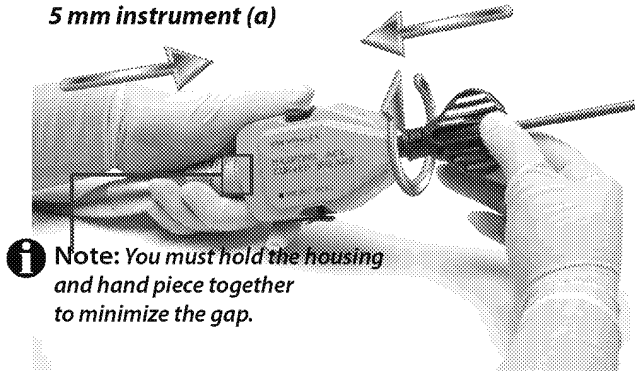


Figure 9.8 Use only the wrench for 5 mm instrument

Note: If you do not hear the click after several turns of the wrench, pull the insert partially out of the housing, rotate the insert 180 degrees and re-engage into the housing.

3. Slide the wrench off the insert, over the closed jaws, and remove it completely.
4. Confirm that the insert is securely attached to the housing by trying to slide the insert out while holding the housing.

Generator Self-Test

CAUTION: The *da Vinci Harmonic ACE* Curved Shears can only be used a compatible Ethicon Endo-Surgery Generator and Hand Piece. It is not compatible with the ULTRACISION Generator (GEN01/GEN32). Refer to the list of Compatible Ethicon Endo-Surgery Generators and Hand Pieces on page 9-3.

Note: Do not turn the generator power on before the hand piece and instrument are connected to the generator.

1. Plug the hand piece into the appropriate generator port.
2. Turn on the generator: press the power button on front panel.

Note: When assembled, the jaws of the device close automatically. The jaws must be open during the generator self-test. An error may occur if the jaws are closed during the generator self-test.

3. **To open the jaws:** As shown in Figure 9.9 below, hold the instrument housing with one hand, and with the other hand push only the plastic ring of the insert toward the housing without touching the hand piece. Holding the hand piece while pushing the insert can cause the self-test to fail.

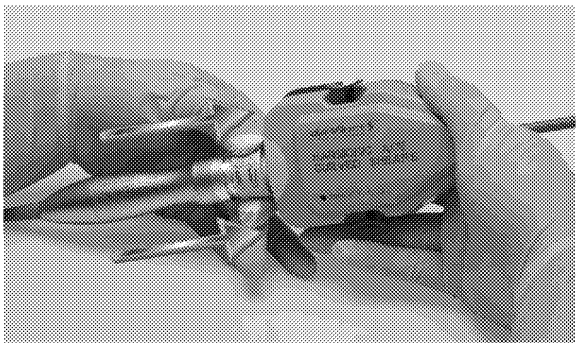


Figure 9.9 Push the insert toward the housing to open the jaws; do not touch the hand piece while pushing

4. With the jaws open and away from any obstruction, activate the Harmonic System by pressing the foot pedal. "TEST IN PROGRESS" will appear on the generator's graphic display and audible tones will indicate the test is in progress. If no errors are identified, the device is ready for use.

- For *da Vinci Si* Systems only, after self-test using the auxiliary Ethicon foot pedal, the ISI energy activation cable for Ethicon generators (PN 371870) can be connected directly from the **Energy** connector on the Core to the back of the generator, replacing the auxiliary Ethicon foot pedal. This enables the surgeon to activate the generator through the associated Surgeon Console pedals.

Insertion and Removal of Device

- Before inserting the device into the sterile adapter and cannula, close the jaws of the instrument.
- During instrument insertion, ensure that the instrument slides smoothly through the cannula. If not, remove and inspect the instrument for damage such as bent shaft. Discontinue use if damage is observed.
- To remove the device, squeeze the release levers on the housing and withdraw the device along the instrument axis.

9.3 Intra-Operative Use

The *da Vinci Harmonic ACE* Curved Shears should be used only by a physician or medical personnel under the supervision of a physician.

Use the *da Vinci Harmonic ACE* Curved Shears for dissection, grasping, coagulation, and cutting between the blade and clamp arm. Use the outside edge of the blade for backcutting.

Note: Keep the clamp arm open when backcutting, or while the blade is active without tissue between the blade and tissue pad, to avoid damage to the tissue pad.

1. Select the desired minimum (MIN) power level using the INCREASE and DECREASE buttons on the generator. Refer to the Generator Manual for detailed instructions.

Note: The recommended minimum (MIN) starting power level is Level 2. For greater tissue cutting speed use a higher generator power level, and for greater coagulation use a lower generator power level. The amount of energy delivered to the tissue and resultant tissue effects are a function of many factors, including the power level selected, blade characteristics, grip force, tissue tension, tissue type, pathology, and surgical technique.

2. For optimal performance, clean the instrument blade, clamp arm and distal end of the insert throughout the procedure by activating the end of the insert in saline.

Note: Do not touch the device to metal while activated.

Note: Do not clean the blade tip with abrasives. It can be wiped with a moist gauze sponge to remove tissue, if necessary.

3. If tissue is visible in the clamp arm, use hemostats to remove residue with the generator in Standby mode.
4. The blade is ultrasonically energized when you press the applicable footswitch pedal. For *da Vinci* and *da Vinci S* systems, the pedal is attached directly to the Ethicon Generator; for *da Vinci Si* systems, the pedal may be one of the pedals in the Surgeon Console's integrated footswitch panel, or it may be the pedal attached directly to the Ethicon Generator.

Note: Scratches on the blade may lead to premature blade failure.

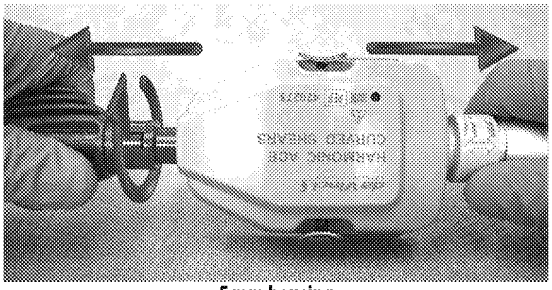
- **Avoid accidental contact with other instruments during use.**
- **Do not use any means other than the blade wrench to attach or detach the instrument from the hand piece.**

9.4 Disassembly and Disposal

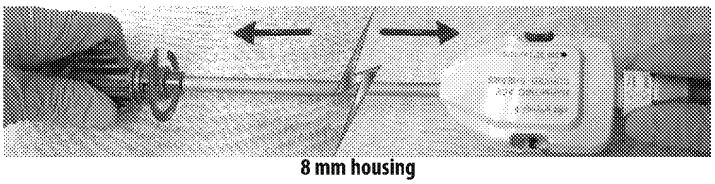
Examine the device thoroughly after each use. If any abnormality is detected, do not use the device and contact *Intuitive Surgical* Customer Service.

Clean the instruments immediately after each use. Do not allow debris to dry on or inside the instrument before cleaning.

1. After each clinical application, turn the generator OFF at the power switch or enter Standby mode.
2. Slide the torque wrench over the jaws of the insert and onto the wrench flats of the housing. While holding the hand piece (do not grasp the housing), turn the wrench counterclockwise several turns, until the housing is free to slide off the insert.



5 mm housing



8 mm housing

Figure 9.10 Removing the insert from the housing

Note: Take care to avoid injury from the blade tip while sliding the torque wrench on or off the insert.

3. Remove the wrench by sliding it back over the insert.
4. While grasping the hand piece, slide the insert out of the housing.
5. Slide the torque wrench over the jaws of the insert and onto the wrench flats. Holding the hand piece, turn the wrench counterclockwise to loosen.

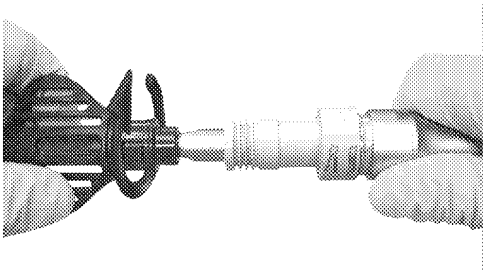


Figure 9.11 Loosening the insert

6. When the insert is loosened, remove the wrench and manually rotate the insert until it separates from the hand piece. See Figure 9.12

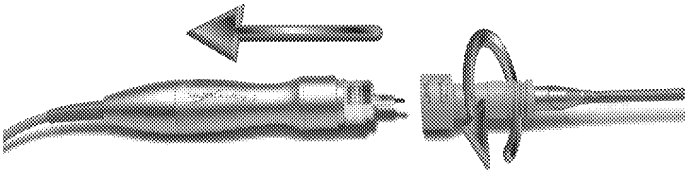


Figure 9.12 Removing the insert from the hand piece

7. Dispose of the insert and the torque wrench in an appropriate container per institution biohazard protocol.

When disposing of this product or any of its components, follow all applicable national and local laws and guidelines.

End of section

10 *EndoWrist One* Suction/Irrigator

10.1 Introduction

This section provides details specific to the *EndoWrist® One* Suction/Irrigator (PN 410299). The *EndoWrist One* Suction/Irrigator is designed to be used with the *da Vinci® Si™* Surgical System.

Note: The *EndoWrist One* Suction/Irrigator (PN 410299) is sterilized with ethylene oxide (EO) and ships sterile. It is for single use only and is not designed to be cleaned, disinfected, or sterilized. Therefore, validated cleaning and sterilization methods and reprocessing instructions are not available for this product.

⚠ CAUTION: DO NOT RE-STERILIZE. DO NOT RE-USE.

Reprocessing and/or reuse of products intended for single use only may result in degraded instrument performance or loss of functionality, and in exposure to viral, bacterial, fungal, or prionic pathogens.

Note: Read Knowing What Applies – Organization of this Manual (page 1-1) to understand what portions of this manual apply to any specific instrument or accessory. If information specific to an instrument or accessory is not supplied in this manual, *Intuitive* supplies it with that instrument or accessory.

Intended Use

The *EndoWrist One* Suction/Irrigator, when attached to an external suction/irrigation source(s), is intended for use with the *da Vinci Si* Surgical System as a general purpose suction and/or irrigation device used during surgical procedures.

Compatibility Information

The *EndoWrist One* Suction/Irrigator is compatible for use with *the da Vinci Si* Surgical System; it is not compatible for use with the *da Vinci* or the *da Vinci S* Surgical Systems.

The suction tubing can be used with any wall or standalone suction system.

In addition, the *EndoWrist One* Suction/Irrigator is designed for use with a bag of irrigation fluid, pressurized using standard methods for irrigation bag pressurization in the operating room.

Device Description

The *EndoWrist One* Suction/Irrigator has the following features:

- It is a fully disposable instrument with an integrated tubing set (Figure 10.1).
- The surgeon can activate suction and irrigation from the Surgeon Console using the corresponding pair of blue and yellow pedals.

- The patient-side assistant can activate the suction and irrigation valves by hand when used through an assistant port, or when the instrument is attached to the instrument arm. See Figure 10.3 for the location of the manual activation buttons for suction and irrigation.

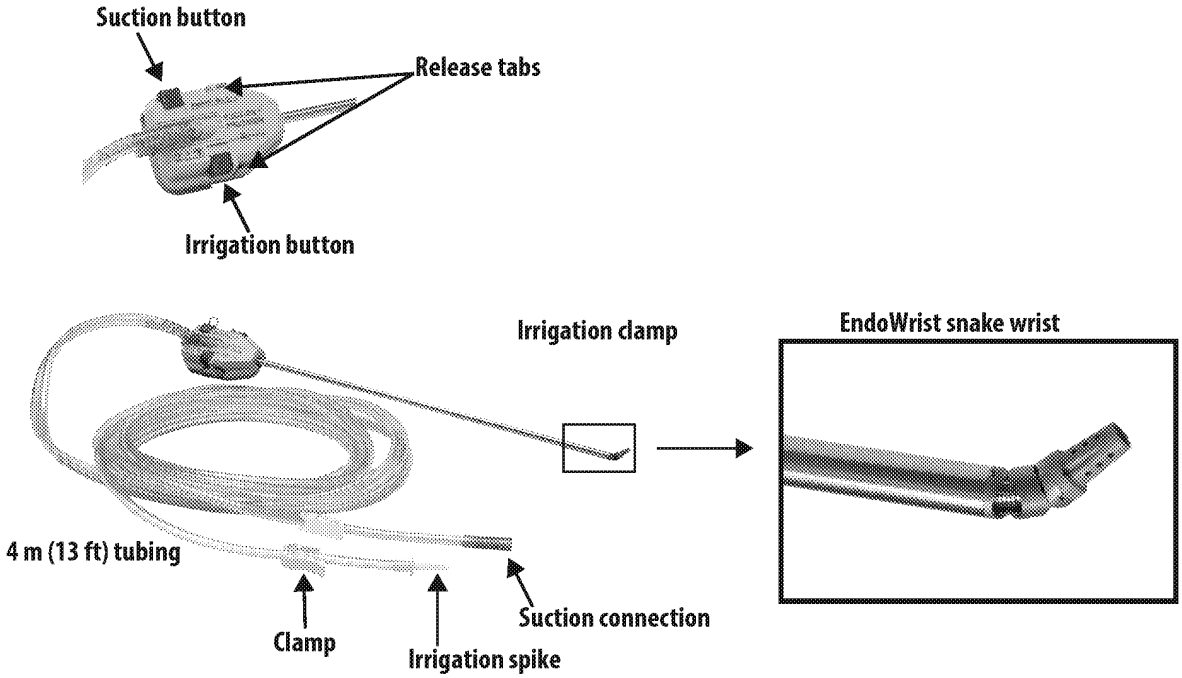


Figure 10.1 EndoWrist One Suction/Irrigator instrument features

10.2 Instructions for Use

Inspection

The *EndoWrist One* Suction/Irrigator is for single use only and comes in a sterile package. Ensure that the packaging has no tears that could lead to contamination of the instrument.

⚠ CAUTION: **Do not use if package is damaged.**

⚠ **CAUTION: A breach in the sterile packaging of the instrument indicates possible contamination. Do not use the instrument if the packaging is not intact.**

Instrument Setup

Instrument setup requires two people, one non-sterile and one sterile. Note which person is responsible for each of the following steps:

1. **Non-sterile person:** Open the sterile tray using aseptic technique and either deposit the instrument onto a sterile table, or have a sterile person remove the instrument and tube set from the tray.
2. **Sterile person:** Pass the tubing ends off to a non-sterile person.
3. **Non-sterile person:** Clamp off the irrigation line on the instrument tubing set using the irrigation clamp provided (Figure 10.2). If desired, also clamp off the suction tubing using the suction clamp provided (Figure 10.2).

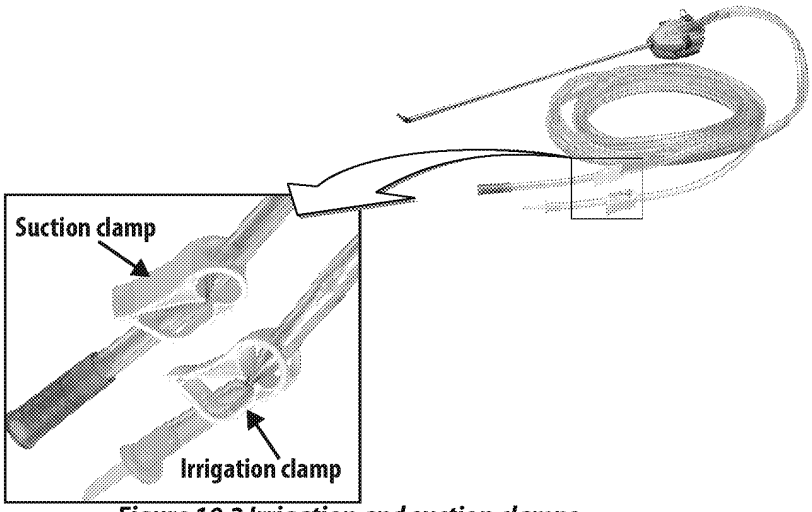


Figure 10.2 Irrigation and suction clamps

4. **Non-sterile person:** Using aseptic technique, remove the cover from the sterile spike and spike the tubing set to the irrigation bag.

⚠ **CAUTION: Ensure that the spike and the bag opening are kept sterile. Follow the manufacturer's instructions for use.**

5. **Non-sterile person:** Pressurize the spiked bag using methods for irrigation bag pressurization commonly used in the operating room, or place it on an IV pole for gravity pressure.
6. **Non-sterile person:** Separate the conjoined tubing so that the suction line can independently reach the suction collecting system.
7. **Non-sterile person:** Connect the suction line from the instrument tubing set to the suction collecting system, open the clamp on the suction tubing, and turn on the vacuum source.
8. **Non-sterile person:** Open the clamp on the irrigation line.

⚠ **CAUTION: Do not exceed an irrigation pressure of 400 mm Hg.**

9. **Sterile person:** With the end of the instrument in a basin, press both the blue irrigation button and the red suction button (Figure 10.3) to prime the instrument and tubing. Hold down both buttons until all of the air is out of the system.

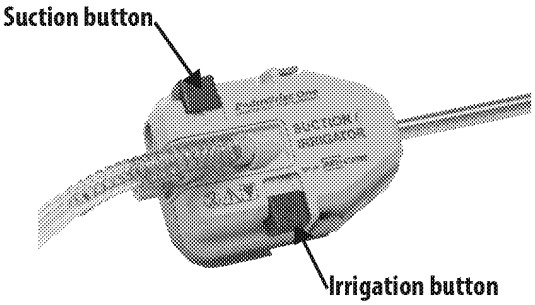


Figure 10.3 Manual control buttons

Intraoperative Use

⚠ CAUTION: Only a physician or medical personnel under the supervision of a physician should use the *EndoWrist One* Suction/Irrigator.

⚠ CAUTION: Intraperitoneal pressure monitoring is mandatory when using this device.

⚠ CAUTION: When the instrument is fully articulated, use caution when applying force to the end of the instrument. Excessive force may result in instrument damage.

⚠ CAUTION: Do not use this instrument to apply force to bone or other hard objects, because it may result in instrument damage.

Note: While the suction/irrigator is not an electrosurgical instrument, the surgeon can activate it with the same pedals used to activate electrosurgical instruments. Therefore, observe the following caution.

⚠ CAUTION: Inadvertent electrosurgical energy may cause serious injury or surgical complications to the patient. It is important to ensure a full understanding of the *da Vinci* Surgical System energy user interface and use caution when working near critical anatomy.

Surgeon Console Activation

Note: Before installing the instrument, manually straighten the wrist and ensure the tubing path is free from potential collisions, kinks, and has enough slack to allow for insertion and manipulation of the instrument.

Note: Be careful to maintain the sterility of the instrument tubing during all modes of use. *Intuitive* recommends use of atraumatic clamps to secure the tubing to the sterile drapes on the OR table or back tables.

To operate the instrument once installed and in following mode:

- Press the blue pedal to activate suction (Figure 10.4).
- Press the yellow pedal to activate irrigation (Figure 10.4).

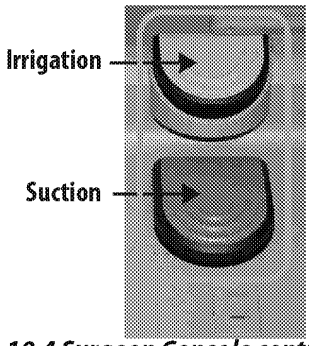


Figure 10.4 Surgeon Console controls

Note: The *EndoWrist One* Suction/Irrigator instrument has less overall range of motion at the instrument tip than other 8 mm *EndoWrist* instruments. In addition, the instrument does not have roll functionality.

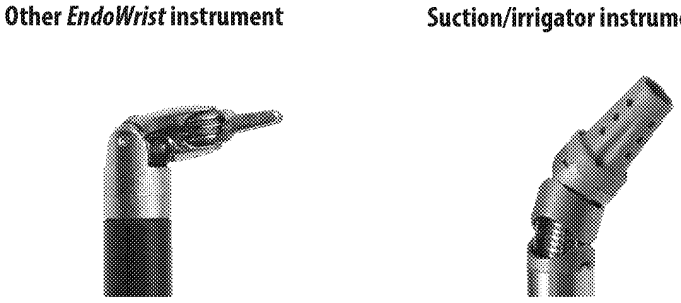


Figure 10.5 Other instrument vs EndoWrist One Suction/Irrigator instrument

Note: Suction or irrigation can be activated at the same time as other energy instruments by pressing the associated foot pedals simultaneously.

Note: If the suction or irrigation valves remain partially open during use and typical measures for clearing the lines (that is, applying irrigation and/or suction) do not result in the valves closing, you can manually pull back the buttons on the instrument or clamp the tubing to stop the leak. Furthermore, if the valve remains partially open during a system fault, resume following and press/release the corresponding Surgeon Console pedal to fully reset the valve position.

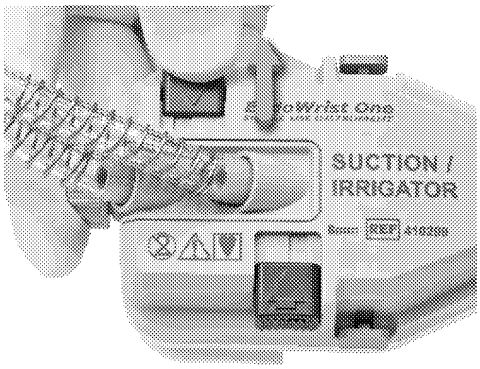


Figure 10.6 Pull back button on instrument to stop leak

Note: When not using suction, make sure that the red suction button does not remain depressed, so as to minimize loss of pneumoperitoneum.

Note: Prior to removal, make sure the wrist is completely straight.

Figure 10.7 Wrist at angle vs wrist completely straight

Patient-Side Activation

You can manually activate suction or irrigation by pressing the blue irrigation button or red suction button on the instrument housing. These buttons work at any time the instrument is properly attached to suction and irrigation sources, whether installed on an instrument arm or using the suction/irrigator as an independent laparoscopic instrument through a dedicated 8-12 mm assistant port. Furthermore, these buttons work whether activated from the Surgeon Console or not.

Note: Before inserting or removing the suction/irrigator through the assistant cannula for manual use, make sure the wrist is straight.

- To activate irrigation, press the blue irrigation button (Figure 10.8).
- To activate suction, press the red suction button (Figure 10.8).

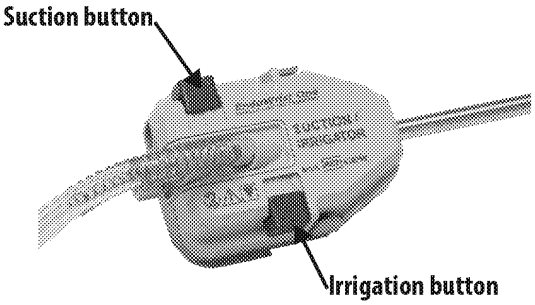


Figure 10.8 Patient-side activation of irrigation, suction

Note: While installed on a robotic arm, the manual suction and irrigation buttons work at all times regardless of arm status, whether in following, clutched, locked, inactive, or not in following. Therefore, while installed on a robotic arm, communication between the console surgeon and assistant is important to coordinate patient-side activation of suction and irrigation.

10.3 Disposal

CAUTION: This instrument is for single use only and must be disposed of as hazardous biological waste.

Before disposing of the instrument, close the irrigation and suction clamps and detach the tubes from the irrigation and suction sources. When disposing of this product or any of its components, follow all applicable national and local laws and guidelines.

End of section

11 Hem-o-lok® Clip Applier

11.1 Introduction

This section contains instructions for use specific to the *EndoWrist*® Hem-o-lok® Clip Applier. Refer to the instrument carton label and instrument housing for the specific instrument and clip compatibility information.

Note: Read Knowing What Applies – Organization of this Manual (page 1-1) to understand what portions of this manual apply to any specific instrument or accessory. If information specific to an instrument or accessory is not supplied in this manual, *Intuitive* supplies it with that instrument or accessory.

Intended Use

The product is intended for use with *Weck*® *Hem-o-lok* ligating clips. Refer to each instrument's carton label and housing for information on *Hem-o-lok* clip compatibility.

Device Description

The *EndoWrist Hem-o-lok* Clip Applier is used for the application of *Weck Hem-o-lok* ligating clips. See the table below for information on compatible clips.

Table 11-1 Approved Third-Party Clips

Instrument	PN	Compatible Clips	Product Code	Manufacturer
Medium-Large Clip Applier		*Weck* Medium-Large (Green) Hem-o-lok Polymer Clips	544230	Teleflex Medical
da Vinci S/Si	420327			
Large Clip Applier		*Weck* Large (Purple) Hem-o-lok Polymer Clips	544240	
da Vinci S/Si	420230			
da Vinci Standard	400230			

General Precautions and Warnings

WARNING: Do not perform grip release on a non-faulted system without first pressing the Emergency Stop button. Failure to observe this warning may result in unintended instrument motion or damage to the grip release mechanism.

WARNING: Rotating the grip release tool too far and/or in the incorrect direction can cause unintended instrument motion or damage to the grip release mechanism.

WARNING: In case of system failure while this instrument is grasping tissue, the grips can be manually opened by inserting the grip release tool into the grip release hole in the instrument housing and carefully turning. Squeeze the release levers and withdraw the instrument. Use visualization of surgical site when inserting the grip release tool, opening jaws, clearing jaws from tissue, and removing the instrument from the system.

Always have a backup instrument available to complete the surgical procedure in case of instrument failure.

11.2 *Weck Hem-o-lok* Ligating Clips

WARNING: All instructions, precautions, and contraindications found with the *Hem-o-lok* ligating clips apply when clips are applied with the *EndoWrist Hem-o-lok* Clip Applier.

Indications

Hem-o-lok ligating clips are intended for use in procedures involving ligation of vessels or tissue structures. Surgeons should apply the appropriate size clip for the size of the vessel or tissue structure to be ligated such that the clip completely encompasses the vessel or tissue structure.

Contraindications

Hem-o-lok Ligating Clips are not intended for use as a fallopian contraceptive tubal occlusion device.

Hem-o-lok Ligating Clips are contraindicated for use in ligating the renal artery during laparoscopic donor nephrectomies.

CAUTION: The clip must be latched to ensure proper ligation of the vessel or tissue. Inspect the ligation site after application to ensure proper closure of the clip. Teleflex Medical recommends ligation of the renal artery, in procedures other than laparoscopic donor nephrectomy (see Contraindications above), with more than one clip on the patient side with a minimum distal artery cuff of 2-3 mm beyond the distal clip (Figure 3). Application of a second clip on all other vessels should be dictated by the surgeon's judgment. Security of the closure should be confirmed after ligation. The *Hem-o-lok* Polymer Ligating Clip is not designated for use as a tissue marker. Before applying a clip, verify the structural size and condition of the vessel or structure and use the proper clip size. Ligating clip systems differ in closure characteristics according to clip design and other variables. It is the responsibility of the user to select structures for the application of clips and confirm clip security after placement, and after the use of other surgical devices in the immediate area of the application.

Note: Hem-o-lok ligating clips are supplied sterile. DO NOT resterilize ligating clip cartridges.

11.3 Instructions for Use

CAUTION: Inspect the grips for damage, bent components, or misalignment before use. If damage is observed, replace the instrument. Instrument could be damaged from mishandling during use or processing. Do not attempt to close the jaw down on a vessel or anatomic structure without a clip properly loaded into the jaws. Closure of empty jaws on a vessel or structure may result in patient injury.

1. To load the clip applier, use only the compatible *Weck Hem-o-lok* clip cartridge. Color coding on the instrument housing matches the color of the ligating clip cartridge with which it is to be used. *Intuitive Surgical* does not assume responsibility for unsatisfactory results caused by the use of any instrument and clip that are not compatible. Ensure that the instrument jaws are fully open. Grasp the instrument at the intersection point of the

two jaws in order to secure the wrist during clip loading. Carefully insert the jaws into the cartridge slot, making sure the jaws are perpendicular to the base of the cartridge. Gently press the applier over the clip until there is an audible click. Slightly rocking the jaws back and forth may assist in loading the clip. Do not force the applier into the cartridge or onto the clip. The applier should enter and withdraw from the cartridge easily.

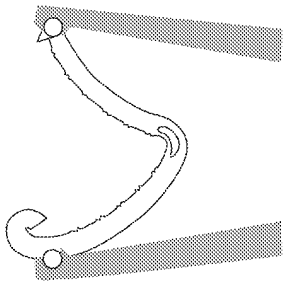


Figure 11.1 Clip loaded in clip applier

2. Remove the applier from the cartridge and confirm that the clip is securely held within the jaws.
3. Close the jaws until the tips of the clip are touching but the clip is not closed. Insert the tip of the instrument through the 8 mm cannula and engage the instrument in the sterile adapter.
4. Once the instrument is inserted and in the surgeon's control, position the clip around the tissue to be ligated. During application, orient the single tooth of the clip as shown (Figure 11.1). This allows the user to visually confirm encapsulation of the structure being ligated. Position the clip around the tissue to be ligated in a manner that provides clear visualization of the locking mechanism (Figure 11.2).

Note: Avoid excess tissue in the locking mechanism of the clip. Squeeze the grips closed until the jaws close and the clip locks shut. Open the grips and withdraw from the ligation site (Figure 11.3).

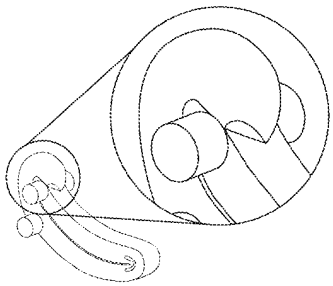


Figure 11.2 Clip locked detail

5. Before instrument removal, make sure that the instrument jaws are in the open position and that the wrist is approximately straight to ensure smooth release of the instrument from the sterile adapter.

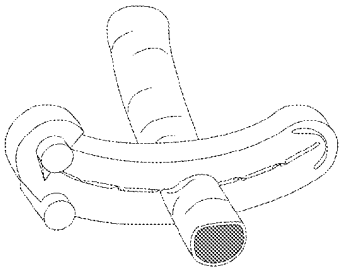


Figure 11.3 Clip applied to vessel

End of section

12 Small Clip Applier

12.1 Introduction

This section contains instructions for use specific to the Small Clip Applier.

Note: Read Knowing What Applies – Organization of this Manual (page 1-1) to understand what portions of this manual apply to any specific instrument or accessory. If information specific to an instrument or accessory is not supplied in this manual, *Intuitive* supplies it with that instrument or accessory.

Device Description

The Small Clip Applier instrument is designed for use with *Weck Hemoclip* small titanium clips. For more information about clip compatibility, see the table below.

Table 12-1 Approved Third-Party Clips

Instrument	PN	Compatible Clips	Product Code	Manufacturer
Small Clip Applier		*Weck*® Hemoclip® Small Titanium Ligating Clips	523835, 523735	Teleflex Medical
da Vinci S/Si	420003			
da Vinci Standard	400003			

12.2 Instructions for Use

Inspect the grips for damage, bent components, or misalignment before use. If damage is observed, replace the instrument.

Loading and Firing a Small Clip Applier Instrument

Note: Order the clips required for the Small Clip Applier instrument (Weck product code # 523835) directly through Weck. *Intuitive Surgical* does not distribute this product.

1. Before inserting the clip, drive the instrument grips open by rotating the yaw-input pulleys (Figure 12.1 A) in the indicated directions.

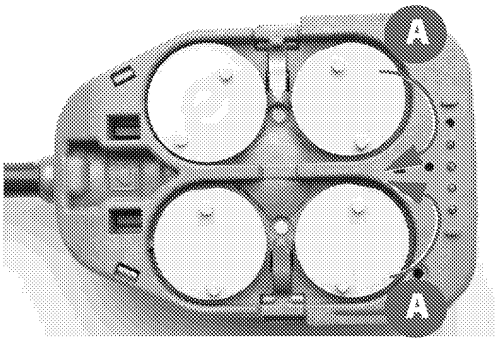


Figure 12.1 Location of yaw-input pulleys

2. Holding the instrument wrist completely straight, firmly press the clip into the grips (Figure 12.2 A). The clip must be flush with the tip of the Clip Applier.

⚠ **CAUTION: If excessive motion of the wrist or grips occurs, the clip should be removed and a new clip inserted. This is because if the wrist moves significantly, the grip action may be affected and the clip could become slightly compressed. This could result in the clip falling out of the grip and into the patient during insertion or engagement. If clip is not flush with the tip of the clip applier, the clip should be removed, grips opened (see step #1) and a new clip inserted.**

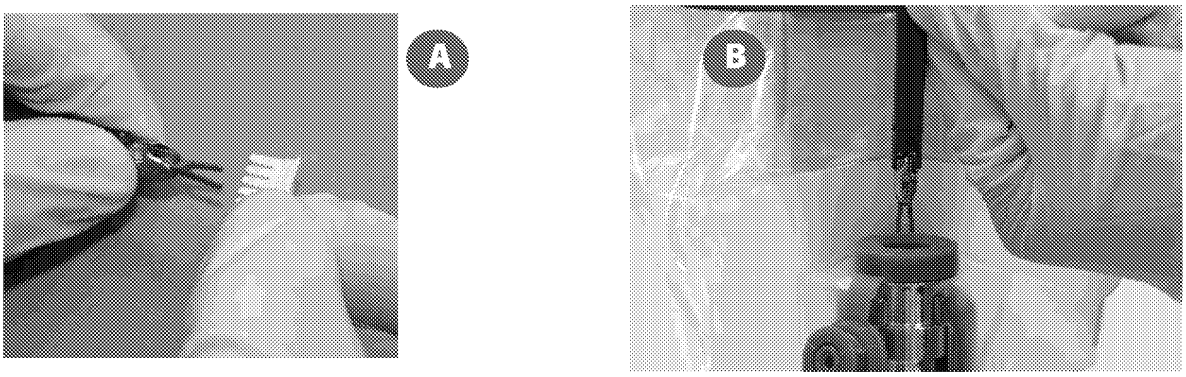


Figure 12.2 Loading clips and inserting the instrument into the cannula

3. Keep the wrist straight while loading the instrument onto the system (Figure 12.2 B).

Note: When preparing to enter the following mode during clip application, the corresponding master controller grip must be at least 90 percent open before the system will enter the following mode. The first movement the surgeon must make is to open the instrument grip slightly via the master controller. This control is used to prevent closing the grip and compressing the clip, which could reduce its effectiveness or cause the clip to fall out of the tool altogether when the surgeon opens the grip after a small closure.

4. When using the system to close a clip, the master controllers should be completely closed at a moderate to fast speed. If the master controllers are not adequately closed, there may be a larger clip gap than required.

End of section

13 *Snap-fit*™ Scalpel Instrument and Accessories

13.1 Introduction

This section contains instructions for use specific for use of the *Snap-fit* Scalpel Instrument and accessories, including the *Snap-fit* 15° Blue Blade (PN 400152), *Snap-fit* Paddle Blade (PN 400158), Insertion Tool (PN 340250) and Blade Protector (PN 340084) designed for use with the *EndoWrist*® *Snap-fit*™ Scalpel Instrument.

WARNING: The *Snap-fit* Scalpel Instrument, used in combination with the *Snap-fit* 15° Blue Blade or *Snap-fit* Paddle Blade disposable accessory tips, should not be used to cut or incise large organs or tissue. If used in this manner, the accessory tip may be damaged and fall into the patient.

Note: Read Knowing What Applies – Organization of this Manual (page 1-1) to understand what portions of this manual apply to any specific instrument or accessory. If information specific to an instrument or accessory is not supplied in this manual, *Intuitive* supplies it with that instrument or accessory.

13.2 Instructions for Use

Insertion Tool

The Insertion Tool for the *EndoWrist*® *Snap-fit*™ Scalpel Instrument is used to assist in the insertion of blades and accessories into the instrument.

1. Using a needle driver with serrated jaws, grasp the base of the blade. Make sure to completely tighten the needle driver onto the blade.

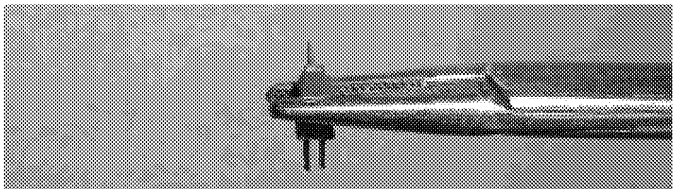


Figure 13.1 Using the needle driver to install the Snap-fit Blade

2. Slide the end of the reusable Insertion Tool (Figure 13.2) with the larger diameter opening over the instrument wrist to help prevent the wrist from moving during blade insertion. Rotate the insertion tool to align the opening at the end with the instrument tip. The insertion tool is properly installed when the tip of the instrument is flush with the edge of the tool.

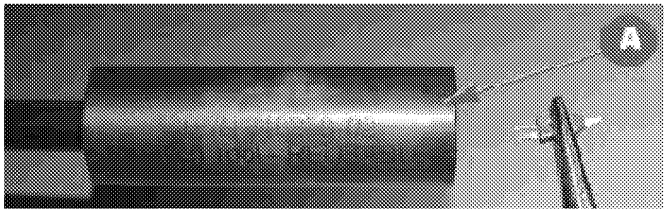


Figure 13.2 Using the insertion tool to attach the Snap-fit Blade

3. Insert the scalpel blade into the wrist until it is firmly seated, as shown. There should be no gap between the accessory tip base and the instrument (see Figure 13.4 for improperly seated *Snap-fit* Blade).

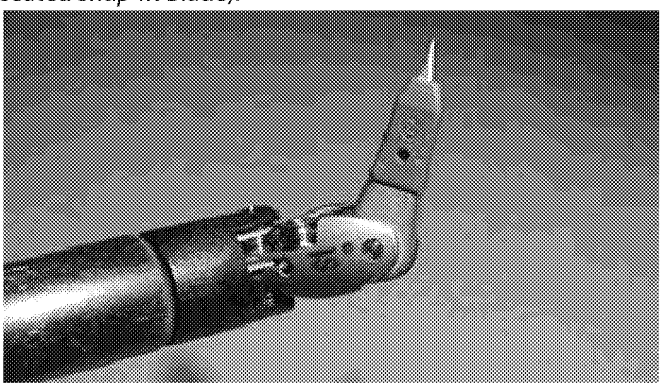


Figure 13.3 Snap-fit Blade installed correctly

- Slide the insertion tool off the instrument before using.

Note: Apply force on the needle driver close to the tip to prevent bending of the tip during insertion.

CAUTION: Scalpel blades are designed for a single insertion into an instrument. If the disposable blade is removed from the instrument tip, it should be properly discarded and a new blade inserted.

An improperly seated tip looks like this.

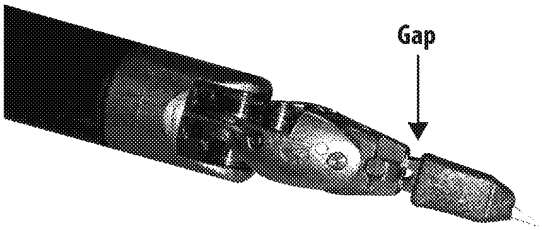


Figure 13.4 Snap-fit Blade installed incorrectly

Note the space between the end of the reusable instrument and the bottom of the base of the disposable scalpel tip. If this occurs, use the Insertion Tool and needle driver again to fully seat the tip.

Blade Protector

The blade protector accessory is used to preserve scalpel sharpness and cannula seal integrity during *Snap-fit* Scalpel Instrument insertion and removal.

1. Before inserting a scalpel instrument into an instrument arm cannula, slide the wider end of the blade protector on to the instrument shaft until the scalpel blade is completely covered by the sleeve of the blade protector (Figure 13.5).

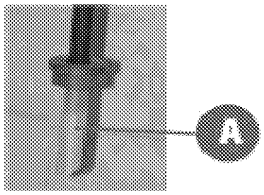


Figure 13.5 Example of blade protector accessory on instrument arm shaft

2. To ease insertion, rotate the blade protector while inserting through the cannula seal. Moistening the cannula seal with saline may aid insertion.
3. After the instrument is engaged into the instrument arm, slide the blade protector up the instrument shaft away from the cannula seal (Figure 13.6).

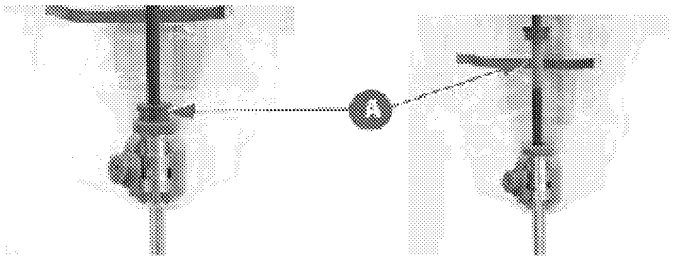


Figure 13.6 Sliding the blade protector up the shaft

4. Immediately before removing a scalpel instrument, slide the blade protector through the cannula seal towards the instrument tip. Be sure to remove the blade protector along with the instrument. If the blade protector remains in the cannula seal, loss of insufflation will occur.

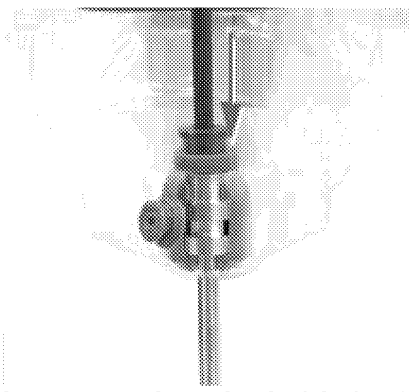


Figure 13.7 Sliding the protector down the shaft before instrument removal

5. When finished with the instrument, slide the blade protector off the instrument and remove the tip.

13.3 Tip Removal

Use a needle driver with serrated jaws to remove *Snap-fit*™ blade tips from the instrument before cleaning the instrument. Grasp the base of the blade firmly and pull to remove the tip. Follow all applicable national and local laws and guidelines when disposing the tips.

End of section

14 EndoPass™ Delivery Instrument

14.1 Introduction

This section contains instructions for use specific to the *EndoPass* Delivery Instrument (PN 400170 & PN 420170) and Blank Cartridges (PN 331788).

Note: Read Knowing What Applies – Organization of this Manual (page 1-1) to understand what portions of this manual apply to any specific instrument or accessory. If information specific to an instrument or accessory is not supplied in this manual, *Intuitive* supplies it with that instrument or accessory.

Intended Use

The *Intuitive Surgical EndoPass* Delivery Instrument is intended for use with the *Intuitive Surgical* Endoscopic Instrument Control System, to facilitate delivery and removal of small surgical accessories endoscopically under direct control of the console surgeon. It is not intended to manipulate or grasp tissue.

Device Description

The *Intuitive Surgical EndoPass* Delivery Instrument is a non-wristed instrument with an interchangeable cartridge used to facilitate delivery and removal of accessories endoscopically in surgical procedures in conjunction with the *Intuitive Surgical* Endoscopic Instrument Control System.

As depicted in Figure 14.1, the *Intuitive Surgical EndoPass* Delivery Instrument consists of an instrument shaft, an interchangeable cartridge at the distal end of the instrument, and housing with release levers that are used to remove the instrument from the sterile adapter of the *Intuitive Surgical* Endoscopic Instrument Control System. Figure 14.1 provides a close up of a blank cartridge.

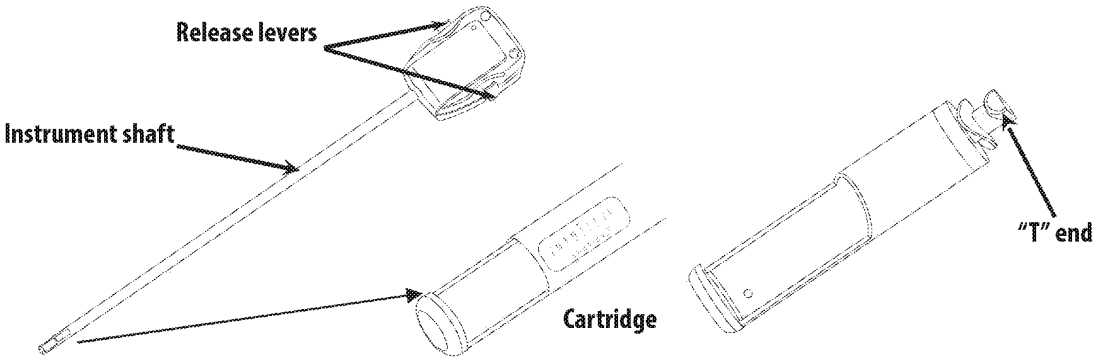


Figure 14.1 EndoPass Delivery Instrument and blank cartridge

General Precautions and Warnings

- Do not use the *EndoPass* Delivery Instrument to grasp or manipulate tissue or bone. Doing so may cause damage to the instrument and tissue.
- Make sure the cartridge is closed before insertion onto the system.

- Always close the cartridge before removing the instrument through the cannula.

14.2 Instructions for Use

Intraoperative Use

Attachment of Cartridge

To attach cartridge to the instrument, hold the instrument shaft in the open position by sliding the outer tube toward the instrument housing and push the "T" end of the cartridge into the end. Rotate cartridge until it drops into the tube and then turn in the direction of the arrow marked on the instrument tube until it snaps in place. When properly engaged, the cartridge opening will line up with the marking on the instrument tube.

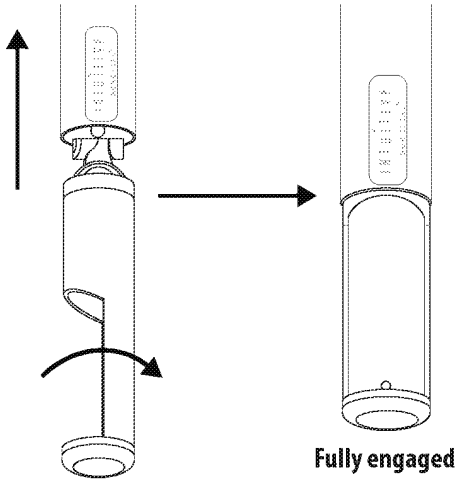


Figure 14.2 Attaching cartridge to instrument

Loading Accessories in the Cartridge

1. Make sure that the cartridge is attached securely to the instrument.
2. Slide the outer tube by hand to expose the cartridge cylinder.
3. Carefully place the surgical accessory to be delivered to the operating site, into the cartridge.

⚠ **CAUTION: The *EndoPass* Delivery Instrument and cartridge accommodate surgical accessories that can securely fit within a 0.272" (6.9 mm) diameter by 1" (25.4 mm) long cylinder. Do not exceed the storage capability of the cartridge or attempt to deliver accessories that do not securely fit in the cartridge. Failure to do so could result in accessories falling out of the cartridge.**

4. After the accessory is securely loaded in the cartridge, slide the outer tube by hand to close the cartridge. Make sure to push the outer tube all the way over the detent to ensure containment of the accessory during insertion.

Delivering an Accessory

1. Insert the instrument through the cannula and engage it into the sterile adapter.

⚠ **CAUTION: If you encounter excessive force during engagement of the instrument with the sterile adapter, do not force insertion. Doing so may result in injury to the patient and damage to the instrument and sterile adapter.**

2. To expose the accessory in the cartridge, carefully squeeze the master grip handle.

Note: The tip of the instrument may move slightly forward if there is excessive friction on the instrument shaft. To minimize occurrence, ensure that there is no interference between the instrument and the cannula.

3. To close the cartridge, simply release the grip pressure on the master handles.

⚠ **CAUTION: Do not close the cartridge if tissue could be trapped. Doing so may cause injury.**

Removing an Accessory

1. With an empty cartridge, insert the instrument with cartridge closed through the cannula and engage it into the sterile adapter as described above.
2. To open the cartridge, carefully squeeze the master grip handle.
3. Place the surgical accessory to be removed into the cartridge.
4. To close the cartridge, release the grip pressure on the master handles.
5. Use the release levers on the instrument to disengage the instrument from the sterile adapter.
6. Pull the instrument straight out until it is completely clear of the cannula.
7. Slide the outer tube by hand to expose the cartridge and remove the accessory.

⚠ **CAUTION: Do not force the removal of instruments with sharp tools as this may result in damage to the sterile adapter.**

14.3 Disassembly Before Cleaning

Detach the cartridge from the instrument before cleaning by reversing the attachment steps above. Hold the instrument shaft in the open position by sliding the outer tube toward the instrument housing. Rotate cartridge in the opposite direction of the arrow marked on the instrument (for cartridge installation) until it snaps out and then it will drop out of the tube.

End of section

15 Using *EndoWrist* Instruments with Cardiac Ablation Probes

15.1 Introduction

This section provides information specifically regarding use of *EndoWrist*® Instruments with cardiac ablation probes.

Users should consider the following before using the *EndoWrist* Instruments and *da Vinci*, *da Vinci S* or *da Vinci Si* surgical systems with cardiac ablation probes:

- Users should have a thorough understanding of the use of the *da Vinci*, *da Vinci S* or *da Vinci Si* Surgical Systems in conjunction with the specific cardiac ablation probe before use. This includes familiarity with all information in the *da Vinci*, *da Vinci S* or *da Vinci Si* Surgical System user manual and the specific ablation probe's instructions for use and manuals provided with the probe and the ablation system.

WARNING: Read and understand all information, including caution and warning information, in the *da Vinci, da Vinci S* or *da Vinci Si* Surgical System User Manual and the ablation system's instructions for use before using the *EndoWrist* Instruments to manipulate and hold cardiac ablation probes.

Note: Read Knowing What Applies – Organization of this Manual (page 1-1) to understand what portions of this manual apply to any specific instrument or accessory. If information specific to an instrument or accessory is not supplied in this manual, *Intuitive* supplies it with that instrument or accessory.

Applicable Ablation Probe and Recommended *EndoWrist* Instrument

- CryoCath SurgiFrost® 10 CryoSurgical Probe is recommended for use with the EndoWrist Cardiac Probe Grasper (400215/420215).

CAUTION: Use only graspers with grips that can adequately grasp and manipulate the ablation probes. Do not use Large Needle Drivers or other graspers with insufficient grip size. This chapter is applicable only for instruments that are adequate for ablation probe manipulation, as indicated below.

15.2 SurgiFrost Probe Instructions for Use

Preparation and Introduction of SurgiFrost Ablation Probe with *EndoWrist* Cardiac Probe Grasper

Prepare the *EndoWrist* Cardiac Probe Grasper and *da Vinci*, *da Vinci S* or *da Vinci Si* Surgical System as described in Chapter 2 EndoWrist® Instruments and in the system user manual.

Prepare the SurgiFrost Probe as indicated in the Instructions for Use provided by the probe manufacturer. Safe use of the specific probes with the *da Vinci*, *da Vinci S* or *da Vinci Si* surgical systems requires adherence to all instructions provided in the probe manufacturer's documentation, including warnings and caution information.

- After successful SurgiFrost Probe preparation, the patient cart operator should introduce the probe into the surgical field while holding and supporting the proximal end (handle) of the probe. The surgeon console operator may then grasp the probe in the operative field using a Cardiac Probe Grasper.
- The SurgiFrost Probe can be grasped anywhere around the bellows.

Using the Cardiac Probe Grasper, manipulate and place the SurgiFrost Probe into the desired position on the target tissue, taking care not to bend the probe at sharp angles or apply excessive force.

SurgiFrost Probe Positioning and Ablation

Once the SurgiFrost Probe is appropriately shaped and positioned on the tissue, the patient-side operator should maintain hold of the probe handle. Ablation may begin as described in the Instructions for Use provided by the probe manufacturer. Once freezing has begun and the probe is in satisfactory contact with the target tissue, the console surgeon should then release the Cardiac Probe Grasper grips, taking care not to alter the shape of the bellows while moving away from the ablation probe. The Cardiac Probe Grasper should not be in contact with the cryoablative portion of the probe during the remainder of the cycle. Doing so may affect the ability of the probe to create the lesion as intended. The patient-side operator maintains stability of the cryoablation probe by holding the probe's handle.

Throughout the ablation cycle, surgeons should ensure that the SurgiFrost Probe remains stabilized on the target tissue. If necessary, the ablation cycle may be de-activated by pressing the "Stop" button on the system's control panel. When the cryoablation cycle is complete, the probe may be removed from the target tissue by following the probe manufacturer's instructions and training. Once it has been removed, the probe may be repositioned and reshaped with the Cardiac Probe Grasper for additional applications as needed.

SurgiFrost Probe Removal

Once the lesion set is satisfactorily completed, the SurgiFrost Probe may be removed from the target tissue by following the probe manufacturer's instructions and training. The surgeon console operator may manipulate / straighten the probe in order to facilitate removal from the patient. The patient-side operator should be prepared to support the probe as the surgeon releases the grips of the Cardiac Probe Grasper and allows the patient-side operator to remove the probe from the patient.

End of section

16 5 mm Monopolar Cautery

16.1 Introduction

This section contains instructions for use specific to the *EndoWrist* 5 mm Monopolar Cautery Instrument and addresses the following:

- Instrument PN 400142
- Instrument PN 420142
- Electrocautery Hook Accessory PN 400156
- Electrocautery Spatula Accessory PN 400160

Note: PN 400156 and PN 400160 are shipped sterile and are for single use only.

Hook and Spatula Accessories Information

CE 0044

The Hook Accessory PN 400156 and Spatula Accessory PN 400160 are made by Microtek Medical and distributed by *Intuitive Surgical*.

Microtek Medical, Inc.
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Manufactured in the U. S. A.

Note: Read Knowing What Applies – Organization of this Manual (page 1-1) to understand what portions of this manual apply to any specific instrument or accessory. If information specific to an instrument or accessory is not supplied in this manual, *Intuitive* supplies it with that instrument or accessory.

Device Description

The *Intuitive Surgical EndoWrist* Monopolar Cautery Instrument is a multi-use endoscopic instrument utilizing a single use, electrocautery tip accessory, to be used in conjunction with the *Intuitive Surgical da Vinci* Surgical System.

As shown in Figure 16.1, the *EndoWrist* 5 mm Monopolar Cautery Instrument consists of:

- An electrocautery tip accessory
- An end effector (distal end of instrument)
- A wrist
- An insulated shaft

- A back end housing with release levers used to remove the instrument from the sterile adapter of the *da Vinci* Surgical System.

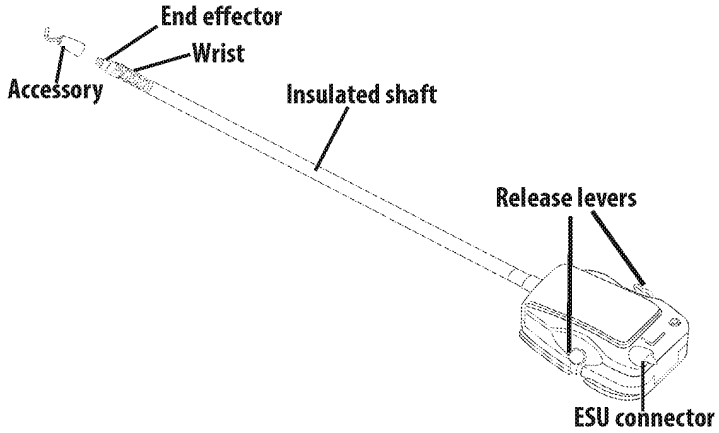


Figure 16.1 EndoWrist 5 mm Monopolar Instrument

General Precautions and Warnings

- The *EndoWrist* 5 mm Monopolar Cautery Instrument must ***always*** be used in conjunction with *Intuitive Surgical* 5 mm metal cannula (PN 313147 for *da Vinci* or PN 420011 for *da Vinci S* or *da Vinci Si*) or with *Intuitive Surgical* 8 mm metal cannula (PN 311954 for *da Vinci*) or (PN 420002 for *da Vinci Si* and *da Vinci S*) and *Intuitive Surgical* metal cannula reducer (PN 371051 for *da Vinci*) or (PN 420019 for *da Vinci S* and *da Vinci Si*).

⚠ WARNING: Failure to use the appropriate cannula will result in electrical arcs from the wrist and alternate site burns due to capacitive coupling.

- The *EndoWrist* 5 mm Monopolar Cautery Instrument should ***never*** be used with any other cannula or trocar system. This restriction includes:
  - Use without a cannula
  - Use with a plastic cannula
  - Use with a non-*Intuitive Surgical* metal cannula system
  - Use with a metal cannula inserted through a plastic cannula

⚠ WARNING: Do not use this instrument to energize the tips of other instruments. This may damage the end effectors or injure tissue inside or outside the field of view. Tissue damage could occur at points near the tip or at the port site (cannula) of the energized instrument.

⚠ WARNING: Exercise caution when working with monopolar instruments close to other instruments. Unintended energy may be delivered from the active monopolar instrument to a second instrument. This could result in burns to tissue in contact with any of the second instrument's metal parts or its cannula. To exercise caution in these scenarios, the monopolar tip should be closer to the tissue than to the second instrument.

- **Do not apply energy when the instrument tip is not in contact with tissue:** Energy should not be applied to an instrument when it is not in direct contact with tissue (referred to as "air-firing"). Additionally, do not use an electrosurgical instrument to apply cautery to any other instrument.
- **Be aware of critical anatomy in contact with the instrument during energy activation:** While activating monopolar energy, be aware of anatomy that is in contact with the instrument wrist or shaft. The instrument should not be used as a retractor while applying energy.
- **Survey the surgical field:** During each procedure, surgeons should survey the surgical field, particularly where the distal end of the instrument shaft may have been in contact with tissue. Survey tissue surrounding the main surgical field, including areas "below" or "behind" the cannula and endoscope that are normally outside the field of view.
- **Consider patient condition:** Before using monopolar cautery in a procedure, consider factors that may make a patient's anatomy and tissue more susceptible to injury from the application of cautery (for example, patients that have received radiation therapy prior to surgery).

16.2 Instructions for Use

⚠ WARNING: The *EndoWrist* 5 mm Monopolar Cautery Instrument should be cleaned and dried before inserting or exchanging any electrocautery tip accessories.

⚠ WARNING: As with any cautery device, it is possible for energy to discharge in an area other than the instrument tip. It is important to exercise caution when using an energized *EndoWrist* 5 mm Monopolar Cautery Instrument to help avoid unintended contact with tissue adjacent to the area to be cauterized.

Inspection Before Use

Examine the instrument before use. In particular, examine the following components for cracks or flaws:

- the shaft insulation
- the metal and plastic components of the electrocautery tip accessory
- instrument cord connector
- the plastic end effector (see Figure 16.1)

⚠ CAUTION: If cracks or other flaws are observed, do not use the instrument. Use of an instrument with such irregularities could result in inadvertent arcing.

Electrocautery Tip Accessory Installation

The electrocautery tip accessory is provided in a sterile pouch for a single use. Install the tip onto the instrument in the sterile field.

1. To install the electrocautery tip accessory (the electrode), insert the metal pin of the electrocautery tip accessory into the slot at the distal tip of the instrument as shown in Figure 16.2.

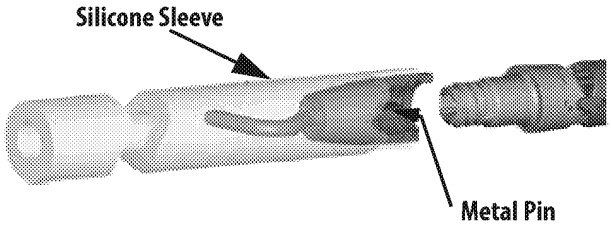


Figure 16.2 Attaching the electrode

2. Grasping the silicone sleeve that protects the electrocautery tip accessory, rotate the accessory until it contacts the sleeve stop, as shown in Figure 16.3.

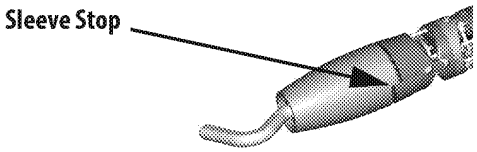


Figure 16.3 Electrode contacting sleeve stop

   The metal electrode will not rotate with the sleeve. Do not over tighten.

3. Remove the silicone sleeve. The silicone sleeve may be discarded or it may be retained to aid in removing the electrocautery tip accessory after the clinical application.

Intraoperative Use

The *Intuitive Surgical EndoWrist* Instrument should be used only by a physician or medical personnel under the supervision of a physician. During use, replace the accessory tip if it appears damaged.

During use, if the tip becomes contaminated by carbonized tissue, remove the instrument and wipe the tip with a piece of moistened, sterile gauze to remove the tissue. Do not use another instrument to clean the tip.

Disassembly

After each clinical application, remove the electrocautery tip accessory by unscrewing the plastic sleeve. To facilitate unscrewing the plastic sleeve, you can reapply the silicone sleeve to the electrocautery tip accessory. When the plastic sleeve disengages the threads on the end effector of the instrument, you can remove the electrocautery tip accessory from the instrument.

⚠ WARNING: Do not attempt to remove the electrocautery tip accessory by turning the metal electrode by hand or with an instrument. This will damage the instrument. Always remove the electrocautery tip accessory by unscrewing the plastic sleeve manually.

Disposal

Discard the electrocautery tip accessory per institution biohazard protocol.

End of section

17 *EndoWrist* 5 Fr. Introducer

17.1 Introduction

This sections provides instructions for use specific to the *EndoWrist* 5 Fr. Introducer, including:

- PN 400225
- PN 420225

Users should consider the following before using the *EndoWrist* 5 Fr. Introducer and *da Vinci, da Vinci S,* or *da Vinci Si* surgical systems with laser energy:

- Users should have a thorough understanding of the use of the *da Vinci, da Vinci S,* or *da Vinci Si* surgical systems in conjunction with the specific laser generators and laser fibers before use. This includes familiarity with all information in the user manual for the applicable *da Vinci, da Vinci S,* or *da Vinci Si* Surgical System, and the instructions for use and/or user manuals provided with the surgical laser systems and fibers.

WARNING: Read and understand all information, including caution and warning information, in the *da Vinci, da Vinci S,* or *da Vinci Si* Surgical System user manual and the appropriate laser surgical system and laser fiber user manuals and/or instructions for use before using the *EndoWrist* 5 Fr. Introducer.

Note: Read Knowing What Applies – Organization of this Manual (page 1-1) to understand what portions of this manual apply to any specific instrument or accessory. If information specific to an instrument or accessory is not supplied in this manual, *Intuitive* supplies it with that instrument or accessory.

Intended Use

The *Intuitive Surgical EndoWrist* 5 Fr. Introducer is intended to be used as a conduit through which compatible surgical laser fibers may be held and directed in conjunction with *da Vinci, da Vinci S, or da Vinci Si* surgical systems. At this time, only the following surgical laser system is compatible for use with the *da Vinci, da Vinci S,* and *da Vinci Si* systems: LISA laser RevoLix® jr. The Laserscope Aura-XP system is only compatible with the *da Vinci* and *da Vinci S* systems because a disposable sterile adapter with filter is not available for the *da Vinci Si* System.

The *EndoWrist* 5 Fr. Introducer may also be used to perform blunt dissection when the laser fiber is retracted or not within the instrument.

CAUTION: The *EndoWrist* 5 Fr. Introducer is only for cleared indications of the *da Vinci, da Vinci S, or da Vinci Si* surgical systems. Users must refer to the Indications for Use located in the Professional Instructions for Use in the *da Vinci, da Vinci S, or da Vinci Si* surgical system user manual.

Overview

Intuitive Surgical EndoWrist instruments used in conjunction with *da Vinci*, *da Vinci S* or *da Vinci Si* surgical systems may be used to manipulate compatible laser fibers. The additional degrees of freedom provided by the *EndoWrist* instrument facilitate precise, tremor-filtered handling of the laser fiber. Enhanced 3D visualization provides the console surgeon with the ability to clearly identify relevant anatomy.

Compatible Surgical Laser Systems and Fibers

Table 17-1 Compatible Surgical Laser Systems and Fibers

Surgical Laser System	Laser Fiber
LISA Laser RevoLix Jr. 15 Watt	LISA Laser WristFib (Ref 101 503 327)
Laserscope Aura-XP™	Endostat 200 micron
	Endostat 300 micron

Contraindications for Laser and/or Laser Fiber Devices

For contraindications applicable to specific laser and/or laser fiber devices, refer to the user instructions provided with that device.

Note: The Laserscope Aura-XP is not compatible with the *da Vinci Si* System.

WARNING: Only the products listed in the table above have been evaluated and found to be compatible for both the laser system and the *Intuitive Surgical da Vinci, da Vinci S,* or *da Vinci Si* surgical system. Use of laser systems or fibers not listed above has not been evaluated by *Intuitive Surgical* and may result in patient or user injury as well as device and equipment damage.

17.2 Instructions for Use

Preparation of the 5 Fr. Introducer Instrument and Accessories

Prepare the *EndoWrist* 5 Fr. Introducer and *da Vinci, da Vinci S,* or *da Vinci Si* Surgical System as described in this manual and the applicable *da Vinci* system user manual.

Prepare the surgical laser system and laser fiber as indicated in the user manual or instructions for use provided by the laser manufacturer. Safe use of the specific fibers with the *da Vinci, da Vinci S,* or *da Vinci Si* surgical systems requires adherence to all instructions provided in the laser and fiber manufacturer's documentation, including warnings and caution information.

Necessary Equipment

- *EndoWrist* 5 Fr. Introducer, PN 400225 / 420225
- Laser Fiber Sheath, PN 400009
- Sterile Adapter with Filter Lenses, PN 311678[1]
- Compatible Surgical Laser System and Fiber

1. Only needed when using the Laserscope KTP system with the *da Vinci* or *da Vinci S* system.

Laser Fiber Sheath Information

CE 0123

The Laser Fiber Sheath PN 400009 is made by LISA laser products and distributed by *Intuitive Surgical.*

LISA laser products OHG
Max Planck Str. 1
37191 Katlenburg Lindau
GERMANY

Distributed by:
Intuitive Surgical
1266 Kifer Road, Sunnyvale, California 94086 • USA
Intuitive Surgical Sàrl
1, chemin des Mûriers, 1170 Aubonne Switzerland
Customer Service from USA 1.800.876.1310
Customer Service from Europe +800.0821.2020
Manufactured in Germany.

Camera Sterile Adapter and Sterile Adapter with Filter Lenses Information

CE

The Sterile Adapter PN 311613 and Sterile Adapter with Filter Lenses PN 311678 are made by Schoelly Fiberoptic and distributed by *Intuitive Surgical.*

Schoelly Fiberoptic GmbH
Robert-Koch-Str. 1-3
79211 Denzlingen
GERMANY

Distributed by:
Intuitive Surgical
1266 Kifer Road, Sunnyvale, California 94086 • USA
Intuitive Surgical Sàrl
1, chemin des Mûriers, 1170 Aubonne Switzerland
Customer Service from USA 1.800.876.1310
Customer Service from Europe +800.0821.2020
Manufactured in Germany.

Assembly Instructions

1. If using the Laserscope system, replace the Camera Sterile Adapter (PN 311613) with the Camera Sterile Adapter with Filter Lenses (PN 311678). The sterile adapter with filter lenses ***must*** be attached before performing the white and black balancing on the endoscopic camera. Otherwise, the camera may not correctly compensate for the green light from the laser during activation and visualization may be impaired. Before each use, ensure that the filter lenses are undamaged and securely in place in the camera sterile adapter. It is not necessary to use the sterile adapter with filter lenses with the LISA laser RevoLix® jr. System.

⚠ **WARNING: The sterile adapter with filter lenses must be used to prevent the Laserscope KTP laser's green light from saturating the endoscopic camera. Use of the Laserscope system without this sterile adapter will impair the view of the surgical field when the laser is activated.**

2. Remove the sterile Laser Fiber Sheath from its packaging. Identify the proximal Touhy-Borst adapter at the proximal end of the sheath, and the sliding Touhy-Borst adapter screwed onto the dispenser tube.
3. Unscrew the luer connector and remove the sheath from the dispenser tube, taking care not to allow the sliding Touhy-Borst adapter to slide off the sheath.
4. Prepare the laser system and fiber according to the user manual and/or instructions for use provided by the laser manufacturer.
5. Advance the laser fiber through the laser sheath until the tip of the fiber is 2 mm from the distal end of the sheath. Tighten the proximal Touhy-Borst adapter to secure the fiber within the sheath. Verify that the fiber is properly secured within the sheath by gently pulling back on the fiber while holding the sheath. When properly secured, no movement of the fiber will occur.

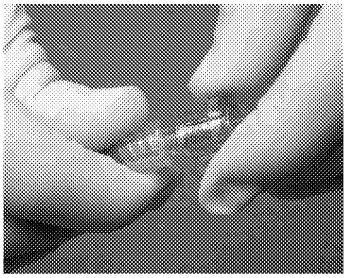


Figure 17.1 Securing the fiber to the sheath

6. Confirm that the wrist of the *EndoWrist* 5 Fr. Introducer is straight. Pass the laser fiber/sheath assembly through the female luer protruding from the back of the instrument as shown below.

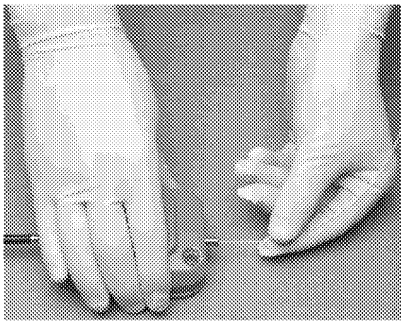


Figure 17.2 Inserting the Laser Fiber Sheath

⚠ **CAUTION: You may feel some resistance as the catheter enters the distal wristed section of the instrument. Do not attempt to force the Laser Fiber Sheath further into the instrument, as this may result in damage to the sheath and/or instrument. If you feel resistance, pull the sheath back slightly, rotate and move forward again.**

7. Advance the sheath into the instrument until it extends past the tip. Retract the sheath slightly, until it is just inside of the tip.

8. Slide the sliding Touhy-Borst adapter along the sheath and twist-lock the luer connector onto the female luer at the back of the instrument. Tighten the Touhy-Borst adapter. Verify that the sheath is properly secured within the instrument by gently pulling back on the sheath exiting the instrument housing. When properly secured, no movement of the sheath will occur.

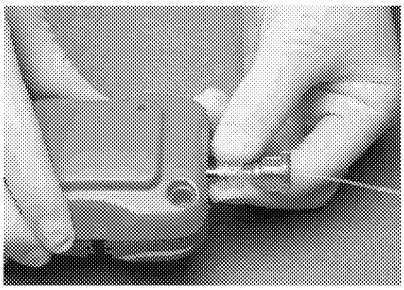


Figure 17.3 Twist-locking the luer connector

9. Install the instrument on the robot and insert into view. Loosen the proximal and sliding Touhy-Borst adapters.
10. Under endoscopic visualization, advance the sheath until it protrudes approximately 2 mm from the tip of the instrument. Advance the fiber until it protrudes 1-2 mm from the tip of the laser sheath.

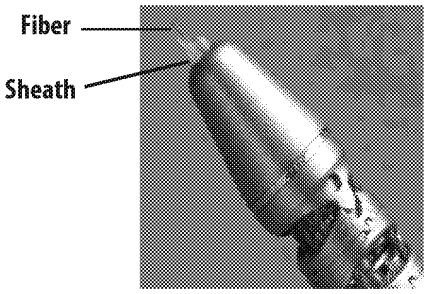


Figure 17.4 Sheath and fiber protrusion

11. Tighten the proximal and sliding Touhy-Borst adapters when desired fiber position is reached. Verify that the fiber and sheath are properly secured. Gently pull back on the sheath exiting the instrument housing and confirm no movement of the sheath occurs. Gently pull back on the fiber exiting the sheath. No motion of the fiber should occur.

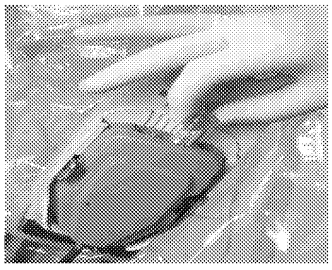


Figure 17.5 Adjusting the Touhy-Borst

⚠ **CAUTION: Do not insert the 5 Fr. Introducer into the instrument cannula with either the fiber or sheath extending past the tip of the instrument. Doing so may cause the fiber or sheath to be damaged.**

⚠ **CAUTION: Before activating the laser, confirm all operating room personnel are wearing appropriate eye protection as specified in the laser manufacturer's instructions for use or user manual.**

Instrument and Laser Use

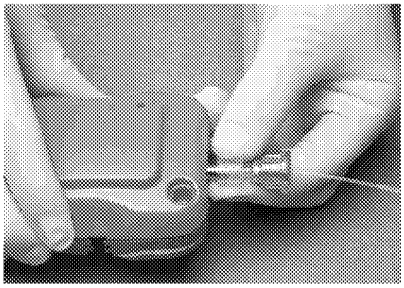
During use of the instrument, the surgeon should make sure the laser fiber is always protruding from the laser sheath. If the laser fiber is drawn into the sheath, damage may occur to the sheath. If damage occurs to the distal end of the Laser Fiber Sheath, cleanly cut the damaged section off at an approximate 45-degree angle and repeat assembly instructions. The laser must be turned off before removing the introducer from the system. If the instrument is removed and re-installed, loosen the Touhy-Borst adapters, withdraw the sheath and fiber into the instrument tip, and re-tighten the Touhy-Borst adapters prior to re-installing and inserting the instrument though the cannula. Follow steps 9-11 to re-install the instrument.

All fiber and laser system use should adhere strictly to the manufacturer's instructions for use.

17.3 Disassembly Instructions

Disassemble the 5 Fr. Introducer before processing the reusable portion of the instrument. In general, the process is the reverse of the assembly instructions. Follow these steps:

1. Remove the instrument from the robot and twist to disconnect the sliding Touhy-Borst adapter from the female luer at the back of the instrument.



2. Confirm that the wrist of the *EndoWrist* 5 Fr. Introducer is straight. Pull out the fiber and sheath from the instrument.
3. Follow all applicable national and local laws and guidelines when disposing the laser fiber and sheath and accompanying Tuohy-Borst adapters and dispenser.

End of section

18 *EndoWrist* Stabilizer System

18.1 Introduction

This section contains instructions for use of the *EndoWrist*® Stabilizer System, including:

- *EndoWrist*® Stabilizer Instrument PN 420182
- *ClearField*™ Tubing PN 420185
- *CardioVac*™ Tubing PN 420186
- *Vacuum Source*™ Tubing PN 420187

Note: PN 420185, 420186, and 420187 are shipped sterile and are for single use only.

CAUTION: **DO NOT RE-STERILIZE.** **DO NOT RE-USE.**

Reprocessing and/or reuse of products intended for single use only may result in degraded instrument performance or loss of functionality, and in exposure to viral, bacterial, fungal, or prionic pathogens.

CAUTION: **Do not use if package is damaged.**

CAUTION: A breach in the sterile packaging of the device indicates possible contamination. Do not use the device if the packaging is not intact.

Note: Read Knowing What Applies – Organization of this Manual (page 1-1) to understand what portions of this manual apply to any specific instrument or accessory. If information specific to an instrument or accessory is not supplied in this manual, *Intuitive* supplies it with that instrument or accessory.

ClearField Tubing and CardioVac Tubing Information

The ClearField Tubing PN 420185 and CardioVac Tubing PN 420186 are made by Microtek Medical and distributed by *Intuitive Surgical*.

CE 0044

Microtek Medical, Inc.
512 Lehmberg Road
Columbus, MS 39704
www.microtekmed.com

EC REP
Microtek Medical B.V.
Hekkenhorst 24
7207 BN Zutphen
THE NETHERLANDS

Distributed by:
Intuitive Surgical
1266 Kifer Road, Sunnyvale, California 94086 • USA
Intuitive Surgical Sàrl
1, chemin des Mûriers, 1170 Aubonne Switzerland
Customer Service from USA 1.800.876.1310
Customer Service from Europe +800.0821.2020
Manufactured in the U.S.A.

Vacuum Source Tubing Set for the Endowrist Stabilizer Information

The Vacuum Source™ Tubing Set for the Endowrist® Stabilizer (PN 420187) is made by Microtek Medical and distributed by *Intuitive Surgical*.

Microtek Medical, Inc.
512 Lehmberg Road
Columbus, MS 39704
www.microtekmed.com

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Intuitive Surgical Sàrl
1, chemin des Mûriers, 1170 Aubonne Switzerland
Customer Service from USA 1.800.876.1310
Customer Service from Europe +800.0821.2020
Manufactured in the U.S.A.

Intended Use

The *Intuitive Surgical EndoWrist* Stabilizer Instrument is intended to be used with the 4th arm *da Vinci S* and *da Vinci Si* Surgical System. The *Intuitive Surgical EndoWrist* Stabilizer Instrument is intended to stabilize the epicardial surface of the non-arrested heart during coronary artery surgery. It is intended to be used only by medical professionals in operating room environments.

Contraindications

This product is not intended for use except as indicated above.

Do not position the stabilizer feet over a coronary artery, newly infarcted or aneurysmal heart tissue.

Device Description

The *EndoWrist* Stabilizer Instrument consists of:

A. The *EndoWrist* Stabilizer Instrument, a multiple-use endoscopic instrument to be used in conjunction with the *Intuitive Surgical da Vinci S* and *da Vinci Si* Endoscopic Instrument Control System. The instrument is compatible with the *da Vinci S* and *da Vinci Si* 12 mm cannula.
B. *ClearField* Tubing, a disposable, prepackaged, sterilized product used to connect the instrument to pressurized irrigation fluid and provide a bloodless surgical field.
C. *CardioVac* Tubing, a disposable, prepackaged, sterilized product consisting of two lines for providing vacuum suction to the Stabilizer feet.
D. *Vacuum Source* Tubing, a disposable, prepackaged, sterilized product consisting of a four-meter vacuum hose to connect from a canister to the CardioVac Tubing lines, and a two-meter tube (with filter) to connect from the canister to a regulated vacuum source.

The *EndoWrist* Stabilizer System components are shown below in Figure 18.1.

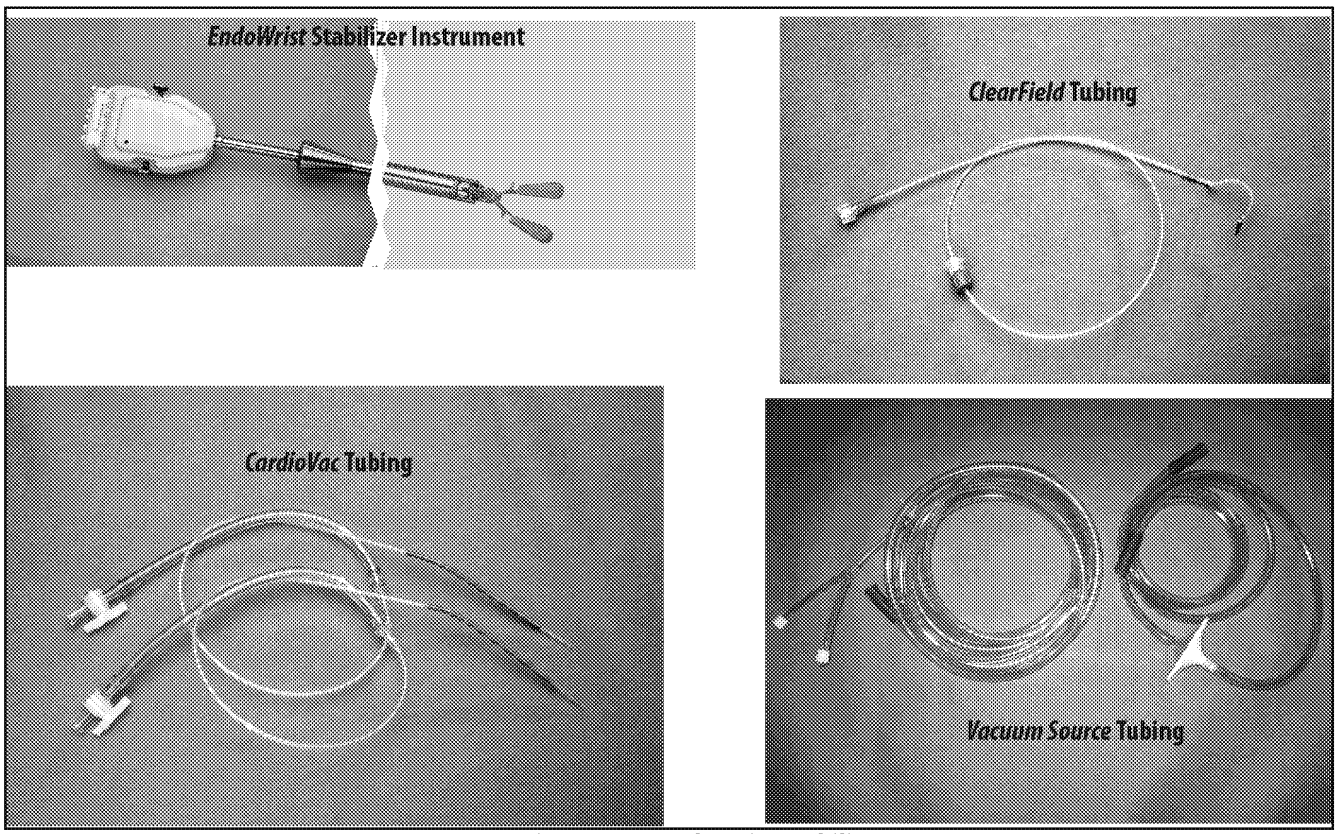

Figure 18.1 EndoWrist Stabilizer System components

General Precautions and Warnings

- Physicians should be properly trained to perform cardiac surgical procedures with *Intuitive Surgical* instrumentation before use. The console surgeon should be trained specifically in the use of a 4th arm *da Vinci S* or *da Vinci Si* Surgical System.
- Many variables, including patient anatomy, pathology and surgical techniques, may influence procedural outcomes. Patient and procedure selection is a responsibility of the medical professional.
- The device is intended solely for use with *Intuitive Surgical* systems.
- This device is intended solely for use through the 12 mm *da Vinci S* or *da Vinci Si* instrument cannula.
- Adequate visualization is required to ensure that the stabilizer feet are not placed over the coronary arteries, or newly infarcted or aneurysmal tissue.
- When removing the stabilizer from the epicardium, care should be taken not to disrupt the anastomotic site.
- Avoid downward pressure against the heart which can cause injury.
- Handle the Stabilizer instrument with care. Avoid mechanical shock or stress that can cause damage to the instrument.

- Do not use another *EndoWrist* instrument to clean debris from the Stabilizer instrument inside the patient. This may result in damage to the instruments or other unintended consequences.
- Avoid vacuum suction greater than (-) 400 mm Hg.
- For removal of the Stabilizer from the surgical field, physicians must first gently return the heart to its unretracted position. Once the heart is in its unretracted position, disengage the stabilizer feet from the heart's surface by turning off the vacuum.

18.2 Instructions for Use

Verify compatibility of all instruments and accessories before using the instrument (refer to General Precautions and Warnings above).

The reusable *EndoWrist* Stabilizer Instrument must be sterilized per instructions before each use.

Inspection Before Use

- Inspect the stabilizer instrument to make sure it has not been damaged and to ensure there are no irregularities. Examples of damage include bent or broken feet at the tip, loose wrist components, frayed or broken cables, cracked or broken pulleys, or cracks on the outer components surrounding the pulleys.
- Check the suction surfaces on the feet for any sharp edges, cracks or roughness, since such deformities could damage the epicardium during surgery or compromise suction performance.
- Ensure that the tubing sets are supplied ***sterile*** in an unopened and undamaged package.

⚠ **CAUTION: If any damage or irregularities are observed, do not use the instrument. Damage or irregularities may compromise patient safety and may result in further equipment damage. Contact *Intuitive Surgical* Customer Service.**

Attaching the Tubing

1. Gently insert the *CardioVac* Tubing down the two lumens marked **"V"** (indicated as A and B in Figure 18.2). Engage the tubing with the luer fittings at this time.

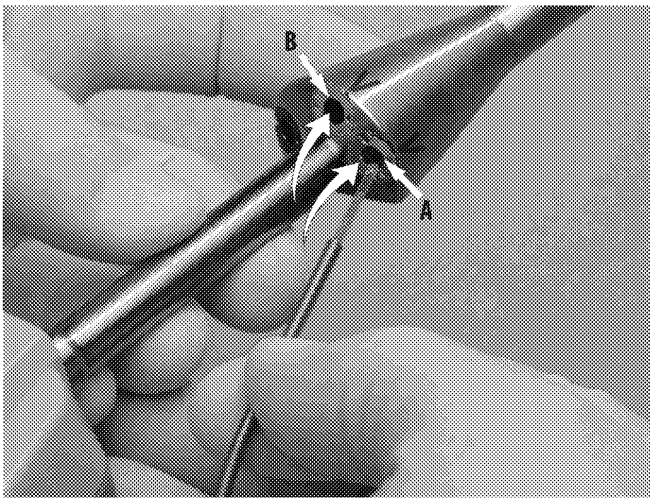

Figure 18.2 Inserting CardioVac Tubing through the lumens

2. Gently insert the tip of the suction tubing into the feet (C) and firmly seat the outer spring (D) into the receptacle (E). You should feel the suction tubing outer spring click in the receptacle.

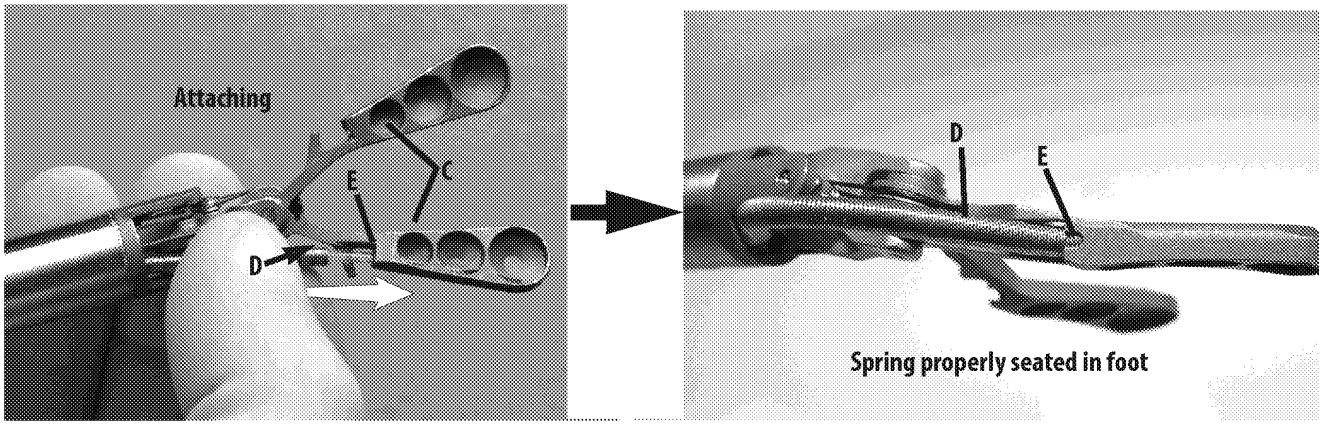

Figure 18.3 Attaching the CardioVac tube and spring properly seated in foot

3. Push the *CardioVac* Tubing stopcocks (F) firmly into the two outer receptacles on the tubing clip (G) at the stabilizer back-end. The stopcocks will snap into place when correctly seated.

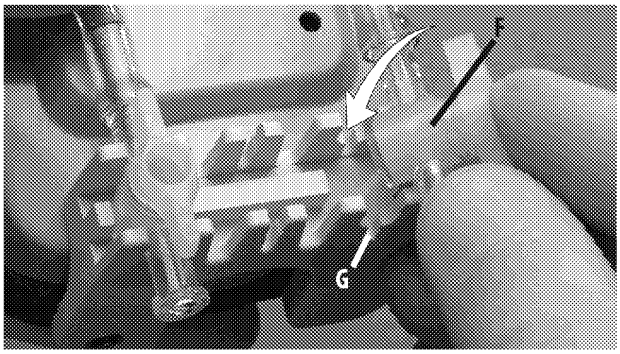

Figure 18.4 Attaching the stopcock in the tubing clip

4. Insert the *ClearField* Tubing down the lumen with the dark colored luer fitting (H), marked "I".

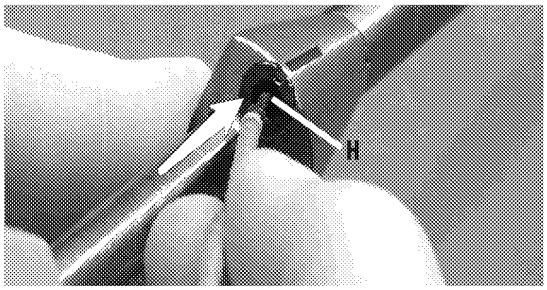

Figure 18.5 Inserting ClearField Tubing through the lumen

5. Advance the tubing down the lumen until the black tip (I) is visible. Do not insert the tubing any farther: the links at the end of the tubing should not be visible.

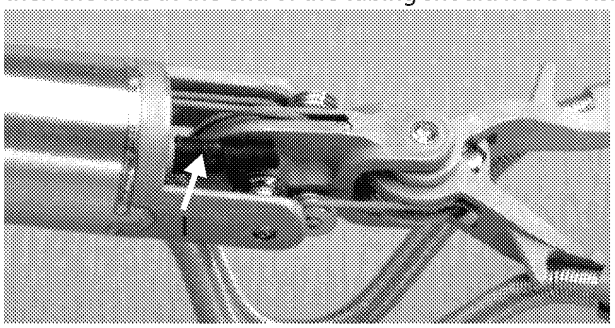

Figure 18.6 Correct setup of the ClearField tip with exposed black tip

6. Connect the compression fitting (J) to the luer fitting on the *EndoWrist* Stabilizer Instrument by pressing and rotating the compression fitting. Gently pull on the compression fitting to confirm that it does not move. Do not tighten the compression nut at this time.

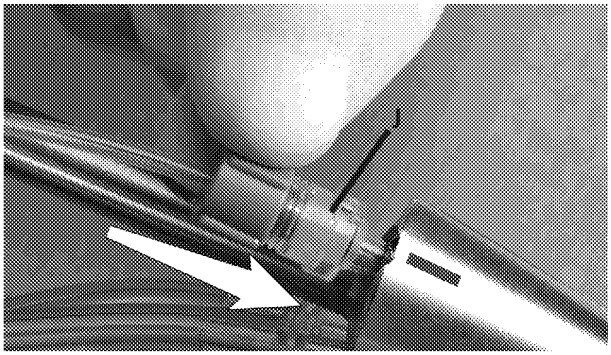

Figure 18.7 Connecting the ClearField Tubing compression fitting

7. Push the *ClearField* Tubing into the middle receptacle on the tubing clip at the back end of the stabilizer. Gently pull back on the *ClearField* Tubing to confirm that it does not move.

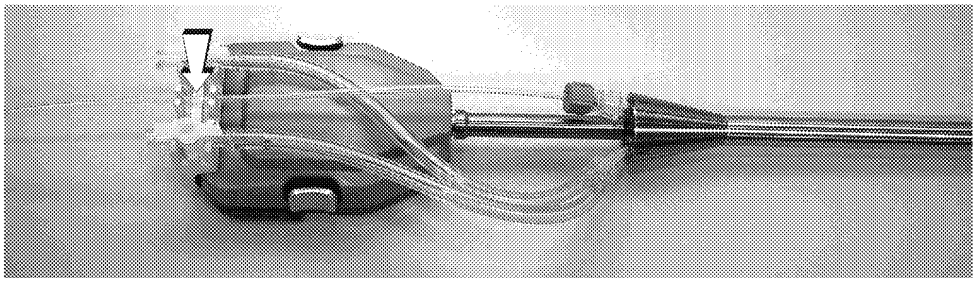

Figure 18.8 Attaching the ClearField tube in the tubing clip

8. Connect the *Vacuum Source* tubing as shown below.

Legend

1. CardioVac Tubing
2. Vacuum Source Tubing, 4m
3. Vacuum canister (not included)
4. Vacuum Source Tubing, 2m with Filter
5. Vacuum regulator (not included)
6. Connection to vacuum source (not included)

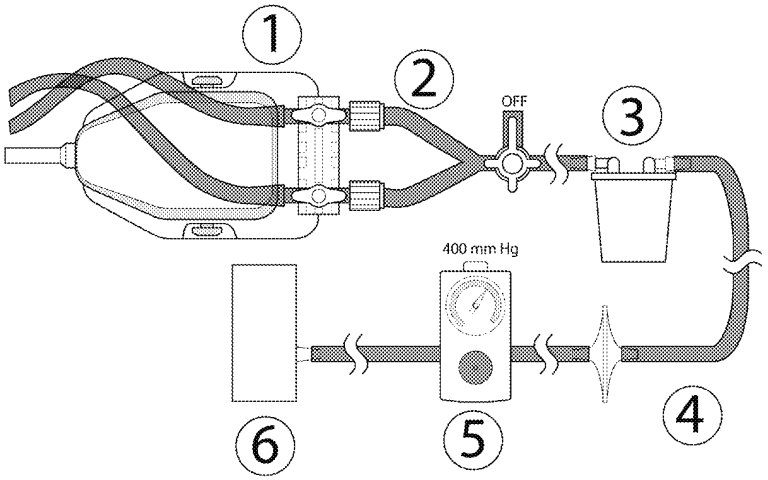

Figure 18.9 Vacuum Source Tubing setup

9. Confirm that all components are properly connected.
10. Connect the *ClearField* Tubing via a sterile IV tubing set to irrigation fluid. Deliver irrigation fluid either with a pressurized bag or manually with a 60cc syringe connected via a three-way valve.

Testing the *EndoWrist* Stabilizer Instrument

Test the suction feet performance before use as follows:

1. Pre-set the vacuum regulator to (-) 400 mm HG (do not exceed (-) 400 mm HG).
2. Attach the "Y" end of the *Vacuum Source* Tubing to the *CardioVac* Tubing on the Stabilizer.
3. Place the Stabilizer feet in contact with the backside of a gloved hand.
4. Open the stopcocks on the *CardioVac* Tubing and the *Vacuum Source* Tubing to test the suction performance.

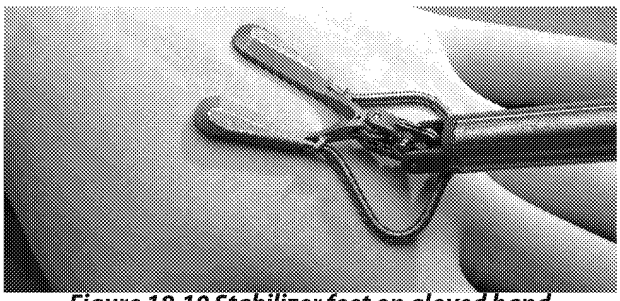

Figure 18.10 Stabilizer feet on gloved hand

5. The feet of the *EndoWrist* Stabilizer should attach firmly. Check that the vacuum regulator display reads (-) 400 mm HG. If the suction performance is inadequate, check for correct assembly of tubing chain starting at the feet. Listen for leaks. Check the vacuum regulator setting and the stopcock positions. If leaks are detected in any of the tubing, replace it.
6. Once adequate suction performance is achieved, close all stopcocks.
7. Disconnect the *Vacuum Source* Tubing from the *CardioVac* Tubing.
8. Store Stabilizer instrument on a sterile scrub table to be readily available for application.

Intraoperative Use

The *EndoWrist* Stabilizer Instrument should be used only by a physician or medical personnel under the supervision of a physician.

- Always use caution when inserting or removing instruments through the cannula.
- Before insertion of the *EndoWrist* Stabilizer Instrument, make sure that the 12 mm *da Vinci S* or *da Vinci Si* instrument cannula is securely attached to the instrument arm.

Specific Precautions and Warnings for Intraoperative Use

- When inserting the *EndoWrist* Stabilizer into the insufflated thoracic cavity, verify that the *CardioVac* Tubing stopcocks are closed and the *ClearField* tubing is capped off to prevent insufflation loss.
- If resistance on introduction into the cannula is encountered, do not proceed with the insertion and check the Stabilizer System for correct assembly or damage. Also check for an obstruction in the cannula. Excessive pushing might cause damage.
- To use the *EndoWrist* Stabilizer Instrument, clear communication between the patient-side personnel (operating the Stabilizer suction and irrigation) and the console surgeon (manipulating and locking the Stabilizer on the heart) is absolutely necessary. Limit noise in the operating room to allow for clear communication.
- If any abnormality or malfunction of the instrument is suspected during use, stop using the instrument and contact *Intuitive Surgical* Customer Service immediately.

- If you do not have a clear endoscopic image, do not manipulate the Stabilizer instrument within the thoracic cavity. Otherwise it may cause perforation, bleeding or damage to the tissue.

Conversion to Conventional Procedure

Should it be necessary to continue the procedure conventionally, we recommend you follow the steps listed below.

Note: For correct removal of the stabilizer instrument from the anastomotic site see instructions below under "Removing the *EndoWrist* Stabilizer System from the Patient." It might be necessary to use the emergency release key for *EndoWrist* Instruments, so have it sterilized and readily available.

1. Remove all instruments except the *EndoWrist* Stabilizer from the patient.
2. Disconnect the instrument arms from the empty cannulae. Move each disconnected arm away from the patient.
3. Remove the *EndoWrist* Stabilizer from the patient.
4. Disconnect the stabilizer arm from the cannula and move the arm away from the patient.
5. Remove the endoscope from the patient and move the camera arm away from the patient.

Insertion of Stabilizer Instrument and Readiness for Application

1. Push the stabilizer feet together and straighten the wrist so the feet will fit through the cannula.

2. ***Important:*** Unseat the luer fittings of the *CardioVac* Tubing and slightly withdraw from the Stabilizer instrument, just enough to minimize the excess tubing at the wrist of the Stabilizer.

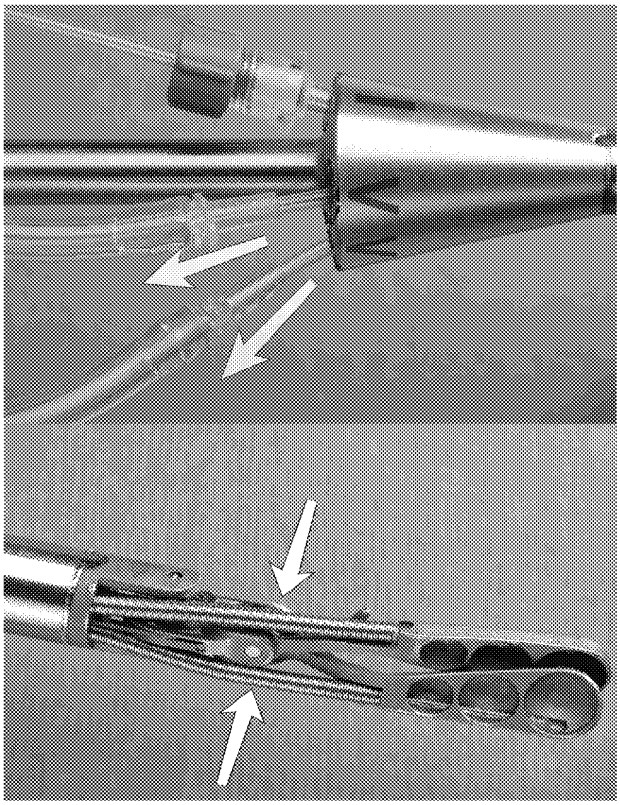

Figure 18.11 Removing excess tubing at wrist

3. Insert the instrument through the 12 mm cannula and engage it on the sterile adapter.
4. Advance the instrument out of the cannula, so that the wrist of the instrument is visible in the endoscopic view.
5. Re-seat the luer fittings of the *CardioVac* Tubing to maximize the excess tubing at the wrist of the Stabilizer. Gently pull on the compression fitting to confirm that it does not move.

Using the *EndoWrist* Stabilizer Instrument Intraoperatively

Note: Please refer to the *da Vinci S* or *da Vinci Si* System user manual for all 4th arm related controls and precautions.

1. With the Stabilizer in following and the Stabilizer feet opened so that they are parallel with each other (not fully opened), align the feet and move toward the heart until both feet are in contact with the tissue.

CAUTION: Do not push the edges of the Stabilizer feet into the epicardium!

2. Activate suction by opening the *CardioVac* Tubing stopcocks and *Vacuum Source* Tubing main stopcock.
3. To provide counter traction, adjust the pressure of the feet against the surface of heart and spread the feet to stretch tissue.

4. When the Stabilizer is in the desired position, lock the stabilizer by switching master control away from the stabilizer instrument arm.
5. ***Important:*** To avoid accidental or unwanted activation of the Stabilizer instrument, inactivate (*da Vinci S*) or lock (*da Vinci Si*) the Stabilizer instrument arm.
6. Advance the *ClearField* Tubing and position the tip over the target site. To hold the tip in the desired location, tighten the compression nut. Gently pull back on the *ClearField* Tubing to confirm that it does not move. See Figure 18.7

⚠ **CAUTION: Do not advance the *ClearField* Tubing by pulling it with an instrument. Doing so may damage the *ClearField* Tubing.**

7. Re-clip the *ClearField* Tubing. Provide sufficient excess tubing to allow full rotation of the instrument shaft. Test irrigation by allowing irrigation fluid to flow freely for a moment.

Readjusting the *EndoWrist* Stabilizer Instrument During a Procedure

If readjustment of the stabilizer is necessary during the course of the procedure, follow these steps:

1. Activate (*da Vinci S*) or unlock (*da Vinci Si*) the Stabilizer instrument arm.
2. Perform an arm swap to control the Stabilizer.
3. To position and place the Stabilizer, follow the instructions in the previous section, Using the EndoWrist Stabilizer Instrument Intraoperatively, page 18-10.

Removing the *EndoWrist* Stabilizer Instrument from the Patient

1. Ensure that the Stabilizer instrument arm is selected and the Stabilizer instrument can be manipulated (see above).
2. Unclip the *ClearField* Tubing and pull it back into the *EndoWrist* Stabilizer lumen to avoid contact with the beating heart.
3. Close the *EndoWrist* Stabilizer feet slightly to release tension on the tissue.
4. Ease the *EndoWrist* Stabilizer feet away from the heart to its unretracted position.
5. Turn off the suction by closing the *CardioVac* Tubing stopcocks and *Vacuum Source* Tubing main stopcock.
6. Move the Stabilizer feet away from the heart.

⚠ **CAUTION: When removing the Stabilizer from the epicardium, care should be taken not to disrupt the anastomotic site.**

7. ***Important:*** Before removing the instrument through the cannula, straighten the instrument wrist. Unseat the luer fittings of the *CardioVac* Tubing and slightly withdraw from the Stabilizer instrument, just enough to remove the excess tubing at the wrist (see Figure 18.11). Also withdraw the ClearField Tubing into the lumen.
8. Squeeze the release levers on the Stabilizer housing and carefully withdraw the instrument. You may need to rotate the instrument shaft and guide the tubing at the back of the instrument to clear the sterile adapter.
9. After use, remove the tubing from the stabilizer and discard the disposable materials according to approved hospital procedures.

End of section

19 Cannulae, Obturators and Accessories

19.1 Introduction

This section contains instructions for use specific to the *Intuitive Surgical* cannulae, obturators and related accessories for the *da Vinci, da Vinci S* and *da Vinci Si* surgical systems. For components identified as having separate instructions for use, please refer to those for sterilization instructions and refer to the manufacturer's guidelines when using OEM accessories with *Intuitive Surgical* cannulae.

Note: Cannulae and accessories are shipped non-sterile unless otherwise indicated in the device's labeling. Clean and sterilize before use.

Note: Read Knowing What Applies – Organization of this Manual (page 1-1) to understand what portions of this manual apply to any specific instrument or accessory. If information specific to an instrument or accessory is not supplied in this manual, *Intuitive* supplies it with that instrument or accessory.

Information on CE Marking of OEM Devices

Part Number (PN) and Products		EC REP	CE	Distributor:
PN 400216 Bladeless Obturator PN 420023 Bladeless Obturator PN 420024 Bladeless Obturator, Long	Teleflex Medical 2917 Weck Drive RTP, NC 27709 U.S.A.	Teleflex Medical IDA Business and Technology Park, Dublin Road, Athlone, Co. Westmeath, IRELAND	CE0120	Intuitive Surgical1266 Kifer Road, Sunnyvale, California 94086 • USA Intuitive Surgical Sàrl, 1, chemin des Mûriers, 1170 Aubonne, SWITZERLAND Customer Service from USA 1.800.876.1310 Customer Service from Europe +800.0821.2020
PN 400161 Cannula Seal PN 420206 Cannula Seal	Applied Medical Resources Corporation, 22872 Avenida Empresa, Rancho Santa Margarita, CA 92688, U.S.A.	Applied Medical Europe BV, Wiekenweg 21, 3815 KL Amersfoort, THE NETHERLANDS	CE0843	

Intended Use

The cannulae, obturators and related accessories have applications in endoscopic surgery to establish a port of entry for *Intuitive Surgical*'s *EndoWrist* instruments, endoscopes, or compatible accessories. They are intended to be used only in a medical facility, by trained medical professionals, in accordance with the user manual for the applicable *da Vinci, da Vinci S* or *da Vinci Si* Surgical System. Do not use the cannulae and obturators for any other purpose.

Contraindications

These devices are not intended for use when minimally invasive techniques are contraindicated.

Device Description

The *Intuitive Surgical* cannulae are stainless steel components consisting of a hollow bowl and shaft. Cannulae come in the following lengths:

Table 19-1 Cannulae Lengths

Product	Regular	Long
8 mm Cannula and 8 mm Cannula with Outlet, *da Vinci*	156 mm	205 mm
8.5 mm Endoscope Cannula, *da Vinci*	153 mm	NA
5 mm Cannula, *da Vinci*	161 mm	NA
8 mm Cannula and 8 mm Cannula with Outlet, *da Vinci S & Si*	166 mm	215 mm
8.5 mm Endoscope Cannula, *da Vinci S & Si*	164 mm	NA
5 mm Cannula, *da Vinci S & Si*	169 mm	NA
12 mm Cannula, *da Vinci S & Si*	166 mm	NA
13 mm Stapler Cannula, *da Vinci S & Si*	166 mm	NA
EndoWrist Stapler Cannula, *da Vinci S & Si*	166 mm	NA

The obturators attach to the cannulae and facilitate the introduction of the cannula into the body cavity. The obturators have a variety of tip configurations for different mechanisms by which to enter the body cavity. The obturators are removed before the use of the cannula for instrument or endoscope access.

The 8.5 mm Endoscope Cannula and 8 mm Cannula with Outlet provide an outlet for insufflation or smoke evacuation.

Compatibility Information

The table below lists compatible obturators, seals and accessories for each cannula type used with *da Vinci*, *da Vinci S* and *da Vinci Si* surgical systems.

Table 19-2 *da Vinci* Cannulae, Obturators and Seals

Cannula	Cannula PN	Obturator			Seal*
***da Vinci* Instrument Cannulae**		**Sharp**	**Blunt**	**Bladeless* / Separator***	
8 mm Cannula, Regular	311954	370386	370387	400216	400077
8 mm Cannula w/ Outlet, Regular	400254				
8 mm Cannula, Long	312216	370632	370629	400217	
8 mm Cannula w/ Outlet, Long	400255				
5 mm Cannula, Regular	313147*	313148*	313149*	400162	400161
8 mm to 5 mm Cannula Reducer	371051	NA			
***da Vinci* Endoscope Cannulae**					
8.5 mm Endoscope Cannula	400263	NA	NA	400216	420206

Table 19-3 *da Vinci S & Si* Cannulae, Obturators and Seals

Cannula	Cannula PN	Obturator			Seal*
***da Vinci S/Si* Instrument Cannulae**		**Sharp**	**Blunt**	**Bladeless* / Separator***	
8 mm Cannula, Regular	420002	420005	420008	420023	400077
8 mm Cannula w/ Outlet, Regular	420254				
8 mm Cannula, Long	420004	420010	420009	420024	
8 mm Cannula w/ Outlet, Long	420255				
13 mm to 8 mm Cannula Reducer	420294	NA			
EndoWrist Stapler Cannula Reducer	420377	NA			
5 mm Cannula, Regular	420011	420012	420013	NA	400161
8 mm to 5 mm Cannula Reducer	420019	NA			
12 mm Cannula, Regular	420020	NA	420021	NA	420206
***da Vinci S/Si* Endoscope Cannula**					
8.5 mm Endoscope Cannula	420260	NA	NA	420023	420206
***da Vinci S/Si* Stapler Cannula**					
13 mm Stapler Cannula, Regular	420292	NA	420293	NA	420206
EndoWrist® Stapler Cannula	420375	NA	420376	NA	410351 420206

Note: To maintain pneumoperitoneum, ensure that the cannula seal is firmly secured to the cannula. To confirm secure attachment: Ensure that the 8mm Cannula Seal and EndoWrist Stapler Cannula Seal are visibly seated around the circumference of the cannula bowl. Ensure that the 5mm Cannula Seal clicks into place. Ensure that all four tabs on the 8.5-13mm Seal (PN 420206) are over the cannula lip.

Note: The stapler cannulae and seals listed in the Compatibility Information section (Table 19-4) are compatible with the staplers identified below.

Table 19-4 Compatible Handheld Staplers and Reloads* (for 13 mm Stapler Cannula)

Stapler (Linear Cutter)		Reload		*EndoWrist* Stapler 45 Cannula Kit (PN 420378)	*EndoWrist* Stapler Cannula Seal (PN 410351)	13 mm Stapler Cannula Kit (PN 420295)	8.5-13 mm Cannula Seal (PN 420206)
Description	**PN**	**Description**	**PN**				
EndoWrist Stapler 45 Instrument	410298	Blue Reload Green Reload	41645B 41445G	✓ ✓	✓ ✓		
Ethicon Echelon 45, Regular Length	EC45	Gray Reload	ECR45M	✓		✓	✓
Ethicon Echelon Flex 45, Regular Length	EC45A	White Reload	ECR45W	✓		✓	✓
Ethicon Echelon 45, Long Length	ECLG45	Gold Reload	ECR45D	✓		✓	✓
Ethicon Echelon Flex 45, Long Length	EC45AL	Blue Reload	ECR45B	✓		✓	✓
		Green Reload	ECR45G	✓		✓	✓
Ethicon Echelon 60, Regular Length	EC60	White Reload	ECR60W	✓		✓	✓
Ethicon Echelon Flex 60, Regular Length	EC60A	Gold Reload	ECR60D	✓		✓	✓
Ethicon Echelon 60, Long Length	LONG60	Blue Reload	ECR60B	✓		✓	✓
Ethicon Echelon Flex 60, Long Length	LONG60A	Green Reload	ECR60G	✓		✓	✓
Ethicon ENDOPATH ETS60, Long Length	LTS60A	White Reload Blue Reload Green Reload	TR60W TR60B TR60G	✓ ✓ ✓		✓ ✓ ✓	✓ ✓ ✓
Ethicon ENDOPATH ETS45, Straight, Regular Length	ETS45	Gray Reload	6R45M	✓		✓	✓
Ethicon ENDOPATH ETS45, Articulating, Regular Length	ATS45	White Reload	TR45W	✓		✓	✓
Ethicon ENDOPATH ETS45, Articulating, Long Length	LONG45A	Blue Reload	TR45B	✓		✓	✓
Ethicon ENDOPATH ETS45, Articulating, Regular Length, No Knife	ATS45NK	Green Reload	TR45G	✓		✓	✓

* These items are listed for reference only and have independent instructions for use that you must refer to before use. These items may also be manufactured by an OEM partner and may bear their CE mark.

WARNING: Only the staplers listed above have been validated for use with the listed stapler cannula and seals. Use of staplers that have not been validated may cause loss of insufflation, compromise the performance of the seal, or damage the cannula seals, which can result in foreign material dropping into the patient's body.

CAUTION: Do not use the *EndoWrist* Stapler Cannula or 13 mm Stapler Cannula as a robotic endoscope cannula.

Note: Do not use the 13 mm Stapler Cannula Kit (PN 420295) with the Stapler 45 System.

General Precautions and Warnings

WARNING: The cannula must be used in conjunction with the appropriate *Intuitive Surgical* Cannula Seal in order to maintain pneumoperitoneum. See the tables above for cannula and seal compatibility.

WARNING: Always use the appropriate *Intuitive Surgical* cannula reducer and seal to ensure intuitive motion when inserting *EndoWrist* instruments through cannula with larger inner diameters (e.g., 5 mm instrument with an 8 mm instrument cannula). See the tables above for cannula and seal compatibility.

WARNING: The 8 mm Cannula with Outlet and 8.5 mm Endoscope Cannula accessories must be used with separate accessories to close the outlet to maintain pneumoperitoneum once inserted. Examples include, but are not limited to: stopcocks, screw-on luer caps, extension lines with shut-off clamps, or the insufflation line.

WARNING: Ensure that the outlet attachment is not inadvertently blocked by patient anatomy, other instruments ports, kinked tubing, etc.

CAUTION: To minimize the risks associated with port placement, ensure the following:

- Appropriate patient positioning to shift organs away from the port placement site.
- An adequate level of insufflation.
- Obturator tip is pointing away from major vessels, organs, and other anatomic structures.
- Visualization of the entire insertion of the cannula using an endoscope is preferred.
- Moderate, controlled pressure is employed when placing the cannula and obturator.

WARNING: Ensure instruments inserted through the cannula are straightened before removal.

WARNING: Do not use the *EndoWrist* Stabilizer with the 13 mm Stapler Cannula or the *EndoWrist* Stapler Cannula.

Complications

Potential complications associated with the use of the cannulae, obturators and reducers are the same as those associated with the use of surgical trocars and laparoscopic surgery in general. These potential complications include, but are not limited to, superficial lesions, injury to internal vessels, bleeding, hematoma, injury to the abdominal wall, infection, and peritonitis.

19.2 Instructions for Use

WARNING: For the *da Vinci* Surgical System, use only the same length cannula on all instrument arms. The selected cannula length on the *da Vinci* Surgical System User Interface Panel must match the cannula length being used on the instrument arms of the Surgical Cart. Failure to do so may result in patient injury, instrument damage or improper functioning.

For *da Vinci S* and *Si* surgical systems, the cannula length is automatically detected and set by the system. The *da Vinci S* and *Si* systems are designed to allow use of different length cannulae.

Inspection Instructions

Before use, inspect the cannulae, obturators and reducers for damage or defects. If available, use a *da Vinci* 8 mm Cannula Gage Pin to inspect 8 mm cannulae, or a *da Vinci* 5 mm blunt obturator to inspect 5 mm cannulae, using the instructions below.

WARNING: Do not use a damaged cannula or reducer. Damaged cannulae and reducers may abrade the instrument shaft and generate particles that may fall inside the patient.

WARNING: Cannula defects can be caused by dropping the cannula or handling it roughly.

WARNING: Do not use an obturator with visible cracks or other damage.

Visual Inspection

Hold the item up close and visually inspect for defects. Examples of defects include rough edges, dents, an out-of-round shape, or a bent cannula shaft. Figure 19.1 below shows examples of defective cannulae and a cannula that is not defective.

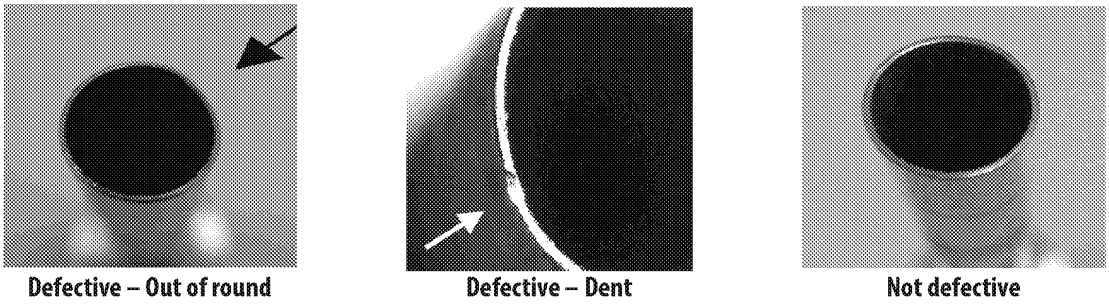

Figure 19.1 Visual inspection examples

Note: Image magnification and special lighting were used in order to capture the images above. However, cannula, obturator and reducer defects can be seen under normal lighting conditions with the naked eye.

Gage Pin Inspection for 8 mm Cannulae

Use the *da Vinci* 8 mm Cannula Gage Pin (PN 710276) for the 8 mm cannula inspection.

Note: The gage pin can be sterilized using the same sterilization parameters as the reusable *EndoWrist* instruments. Refer to the Reprocessing Instructions (PN 550875) for details.

CAUTION: Inspect gage pin for any damage. Do not use a damaged gage pin.

1. Hold the cannula upright.
2. Use your thumb and index finger on the same hand to hold the gage pin above the bowl of the cannula (Figure 19.2).
3. Place your other hand under the tip of the cannula.

4. Drop the gage pin through the cannula and catch it with your hand at the cannula tip.

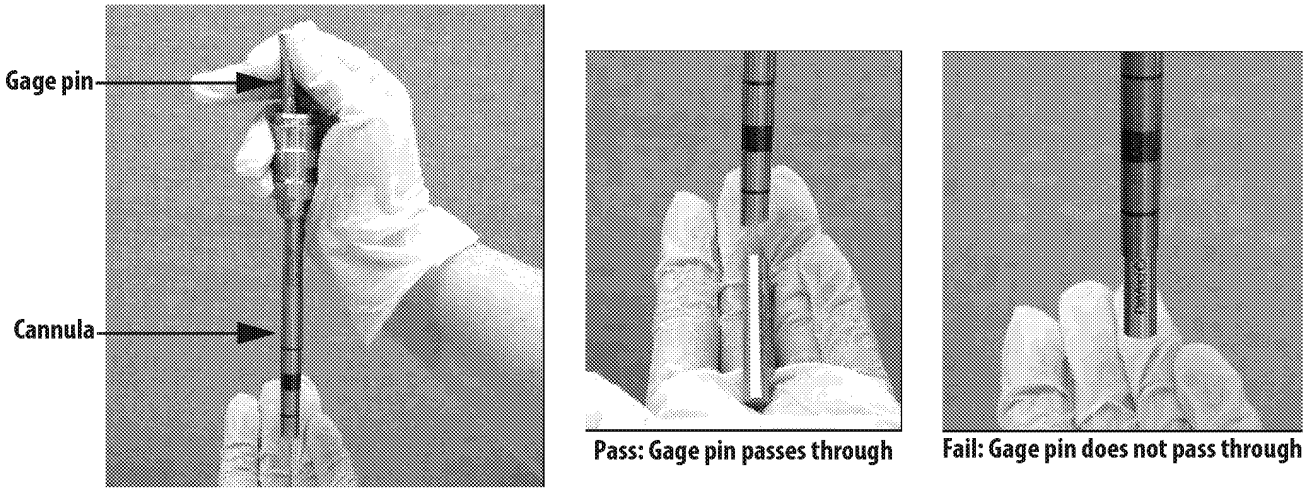

Figure 19.2 Inspection process, and pass and fail examples

Obturator Inspection for 5 mm Cannulae

Use the *da Vinci* 5 mm blunt obturator (PN 420013) for the 5 mm cannula inspection.

⚠ **Caution: Inspect the blunt obturator for any damage. Do not use a damaged obturator.**

Note: First perform a Visual Inspection (see page 19-6) of the cannula for defects.

Note: Do NOT use a cannula seal while performing the inspection below.

1. Hold the 5 mm cannula upright.
2. Insert the 5 mm blunt obturator through the top of the cannula. Maintain control of the obturator – do NOT drop the obturator into the cannula.

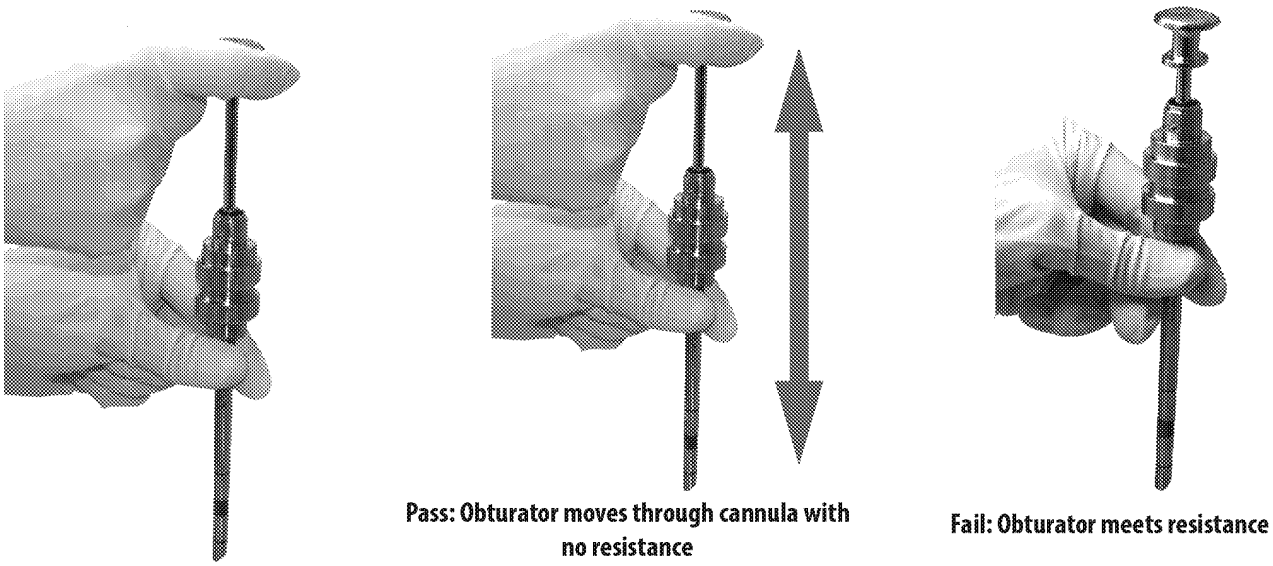

Figure 19.3 5 mm cannula inspection, and pass and fail examples

3. The obturator should be able to move through the cannula without resistance. If there is any resistance while inserting the obturator, do not use the cannula.

Pass/Fail Criteria

The cannula may be used if:

- For 8 mm: the gage pin passes freely through the cannula
- For 5 mm: the obturator moves through the cannula with no resistance
- ***and*** there are no burrs or dents.

The cannula should not be used if:

- For 8 mm: the gage pin does not pass freely through the cannula
- For 5 mm: the obturator meets resistance or gets stuck in the cannula
- ***or*** there are burrs or dents.

Attaching Latching Obturators and Reducers

WARNING: Follow the instructions in this section to ensure complete attachment of a latching obturator or reducer to a cannula. Failure to observe these instructions may result in incomplete attachment and unexpected detachment from the cannula.

When you attach a latching obturator or reducer to an 8 mm, 12 mm or 13 mm Cannula, make sure the latches fasten over the rim of the cannula, as shown on the left in Figure 19.4.

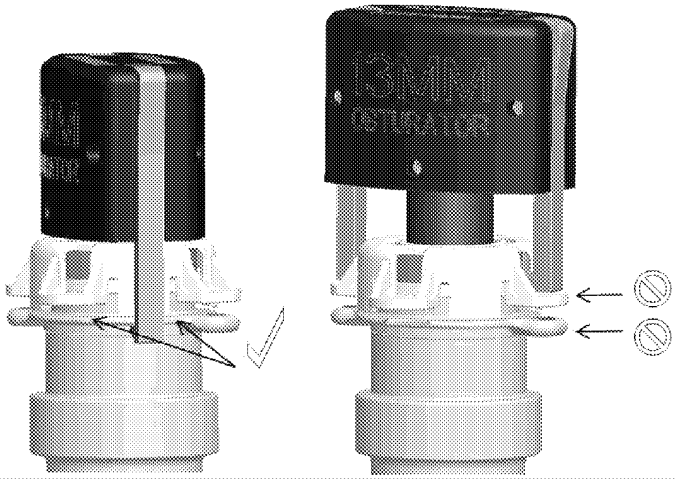

Figure 19.4 Correct (left) and incorrect (right) attachment

Note: The tabs of both the 12 mm Seal and 8 mm or 13 mm Cannula can interfere, as shown on the right in Figure 19.4.

Undocking Required to Use Some Staplers

To install and use some of the compatible staplers (listed in Table 19-4 on page 19-4) through the 13 mm Stapler Cannula and *EndoWrist* Stapler Cannula, you must first undock the cannula from the instrument arm. These staplers have a trigger end that otherwise would interfere

with the instrument arm, preventing stapler installation and use. After undocking, the arm falls away slightly so that you normally can leave the instrument arm where it is, install and use the stapler. After use, re-dock the cannula to the instrument arm.

Intraoperative Use

Only a physician or medical personnel under the supervision of a physician should use *Intuitive Surgical* cannulae, obturators or reducers.

1. Verify that the cannula, obturator and reducer have been appropriately sterilized.
2. Using sterile technique, attach the appropriate sterile cannula seal to the cannula.
3. Insert the obturator fully into the cannula. If using a latching obturator, ensure that the latches are fastened over the rim of the cannula. If using a non-latching obturator, ensure that the obturator is seated firmly against the seal and that the tip of the obturator appears at the distal end of the cannula sleeve.
4. Before introducing the cannula, ensure that the patient is positioned to shift organs away from the port placement site and that an adequate level of insufflation has been achieved.
5. Create a skin incision using standard surgical procedure. Under vision, introduce the cannula and obturator assembly, applying continuous, controlled pressure on the obturator. Make sure that the obutator tip is pointing away from anatomic structures during insertion.
6. When the obturator and cannula are in the abdominal or thoracic cavity, remove the obturator leaving the cannula in place and continue the procedure.
7. The remote center of the cannula (marked with thick black ring) should be placed within the boundaries of the patient body wall according to the specific procedure being performed.

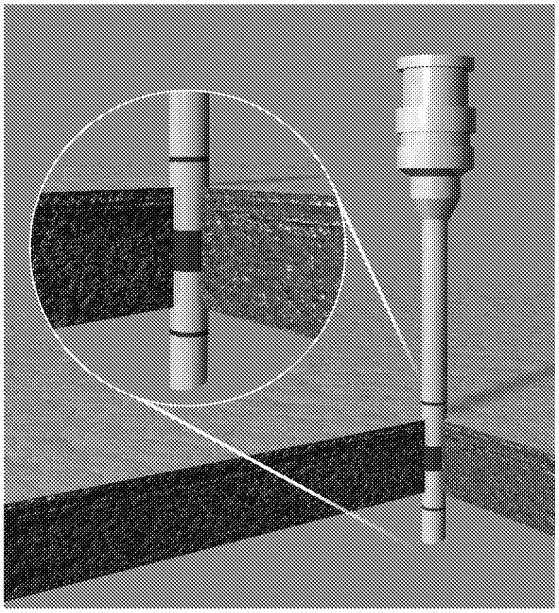

Figure 19.5 Proper placement of remote center

8. Attach the cannula to the system.

- *da Vinci* cannulae connect with the two thumb screws

- *da Vinci S* and *Si* cannulae connect by putting the area with large metal rings within the jaws of the cannula mount.
- Endoscope cannulae attach to the endoscope cannula mount in the area marked by the thick dark band.
- To avoid contact with patient, *da Vinci S* and *Si* cannulae with tabs should be oriented in the cannula mount such that the tabs point to the side.

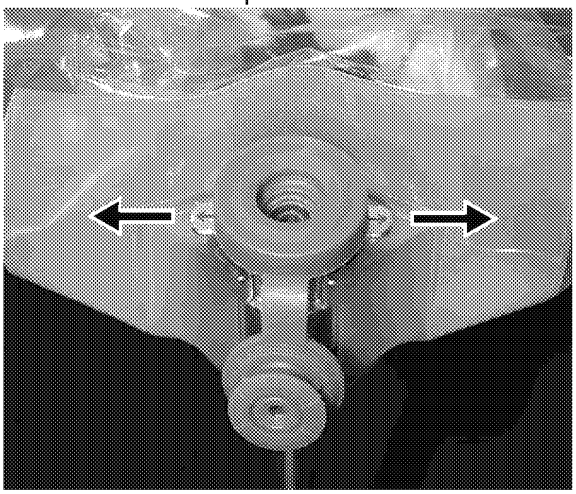

Figure 19.6 Tabs point to the side

9. For the Cannula with Outlet or Endoscope Cannula, using sterile technique, attach the appropriate fitting to the cannula outlet for the desired function of the outlet (insufflation or evacuation).
10. To use *EndoWrist* instruments with larger cannula (e.g., 5 mm instruments with an 8 mm instrument cannula), do the following:
    A. Install appropriate seal on the proximal end of the reducer.
    B. Insert reducer through the seal used for the larger cannula. Slide the cannula section of the reducer into the seal. For the 8 mm to 5 mm Cannula Reducer, the front of the reducer should be facing away from the instrument arm. Slide the reducer down until the latches lock onto the cannula.
    C. Install and use *EndoWrist* instrument.
    D. Remove reducer when reinserting larger instruments or accessories: squeeze the latch levers and lift the reducer out of the seal.
11. For cannula removal, first detach the cannula from the system. Only then remove the cannula from the abdominal or thoracic cavity.

End of section

20 Flared Cannulae

20.1 Introduction

This section contains instructions for use specific to the *Intuitive Surgical* flared cannulae for the *da Vinci, da Vinci S* and *da Vinci Si* surgical systems. Refer to Chapter 19 Cannulae, Obturators and Accessories for related general instructions. Refer to the manufacturer's guidelines when using OEM accessories with *Intuitive Surgical* cannulae.

Note: Cannulae and accessories are shipped non-sterile unless otherwise indicated in the device's labeling. Clean and sterilize before use.

Note: Read Knowing What Applies – Organization of this Manual (page 1-1) to understand what portions of this manual apply to any specific instrument or accessory. If information specific to an instrument or accessory is not supplied in this manual, *Intuitive* supplies it with that instrument or accessory.

Intended Use

The Flared Cannulae are intended to be used with the *da Vinci* Surgical System (*da Vinci S* [Model IS2000] or *da Vinci Si* [Model IS3000]) to serve as a port of entry during *da Vinci* procedures that do not require maintenance of insufflation.

They are intended to be used only in a medical facility, by trained medical professionals, in accordance with the user manual for the applicable *da Vinci S* or *da Vinci Si* Surgical System.

Compatibility Information

The 5 mm Flared Cannula and 8 mm Flared Cannula are compatible only with *da Vinci S* and *da Vinci Si* Surgical Systems; they are not compatible for use with the *da Vinci* Surgical System (Model IS1200).

WARNING: The Flared Cannulae should not be used through the body wall during procedures that require the maintenance of insufflation.

Monopolar Cautery Grounding

When the Flared Cannulae are used with a monopolar energy instrument, capacitive coupling may cause an electrical charge to build up on the cannula because the cannula may not be in direct contact with the patient. To avert this situation, the Flared Cannulae have a grounding receptacle that is compatible with dispersive electrodes with a 2 pin connector and a minimum conductive surface area of 137 cm^2 (Figure 20.1). Dispersive electrodes with this style connector can be found from a number of patient dispersive electrode manufacturers.

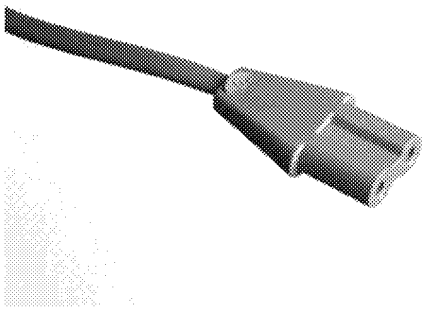

Figure 20.1 Patient dispersive electrode connector

WARNING: For each Flared Cannula through which you use monopolar energy, ensure that an additional patient dispersive electrode is affixed to the patient and plugged into the Flared Cannula (see Figure 20.2 **Cannula and dispersive electrode connection below).**

WARNING: When using the 5 mm and 8 mm Flared Cannulae, limit the maximum ESU power settings to those listed in the chapter named Electrosurgical Unit (ESU) Settings and Energy Activation Cables, in the Instruments and Accessories User Manual (PN 550675).

Note: The patient dispersive electrode attached to the Flared Cannula grounding receptacle is to be used *in addition to* the patient return electrode attached to the ESU generator (see Figure 20.2 **Cannula and dispersive electrode connection below). *Intuitive Surgical* does not provide or sell patient dispersive electrodes. Obtain them from a third-party supplier.**

Device Description

The Flared Cannulae are stainless steel components consisting of a bowl with an integral receptacle for a dispersive electrode connector and a shaft with a flared distal tip. Flared cannulae come in the following lengths:

Part Number	Description	Length
420262	5 mm Flared Cannula, *da Vinci S and Si*	156 mm
420319	8 mm Flared Cannula, *da Vinci S and Si*	154 mm

Note: Since this device is not intended to be used in procedures that require the maintenance of insufflation, obturators, seals and 5 mm and 8 mm reducers are not available for this device.

Note: The *da Vinci S* and *da Vinci Si* systems are designed to allow the use of cannulae of different lengths and diameters; the systems automatically recognize installed cannulae parameters and adjust accordingly.

Complications

Potential complications associated with the Flared Cannulae include improper use of the additional patient dispersive electrodes, which can result in an electrical charge building up on the cannula that could discharge and cause injury to the patient or surgical team.

20.2 Instructions for Use

Inspection

Before use, hold the Flared Cannula up and visually inspect it closely for damage or defects. Examples of defects include bent or broken pins in the grounding receptacle, rough edges, dents, or an out of round shape.

⚠ WARNING: Cannula defects can be caused by dropping the cannula or handling it roughly.

Intraoperative Use

Only a physician or medical personnel under the supervision of a physician should use *Intuitive Surgical* Flared Cannulae.

1. Verify that the cannula has been appropriately sterilized.
2. For each Flared Cannula through which you may use a monopolar instrument during the procedure, install an additional patient dispersive electrode as follows:
   a. Using a sterile technique, affix the patient dispersive electrode to the patient.
   b. Plug the dispersive electrode connector (patient dispersive electrode connector) into the cannula through which a monopolar instrument is to be used (cannula and dispersive electrode connector).
3. Attach the Flared Cannula to the *da Vinci* system instrument arm.

Note: Attach the 5 mm Flared Cannula or 8 mm Flared Cannula to the instrument arm by placing the area with the large metal rings within the jaws of the cannula mount.

Note: Use only 5 mm *EndoWrist* Instruments with the 5 mm Flared Cannula. Use only 8 mm *EndoWrist* Instruments with the 8 mm Flared Cannula.

4. The final configuration should look as shown in Figure 20.2 Cannula and dispersive electrode connection below.

Note: The dispersive electrode placement shown in Figure 20.2 **is a representative illustration. For suggested pad placement of the patient dispersive electrode(s), refer to the manufacturer's instructions for use.**

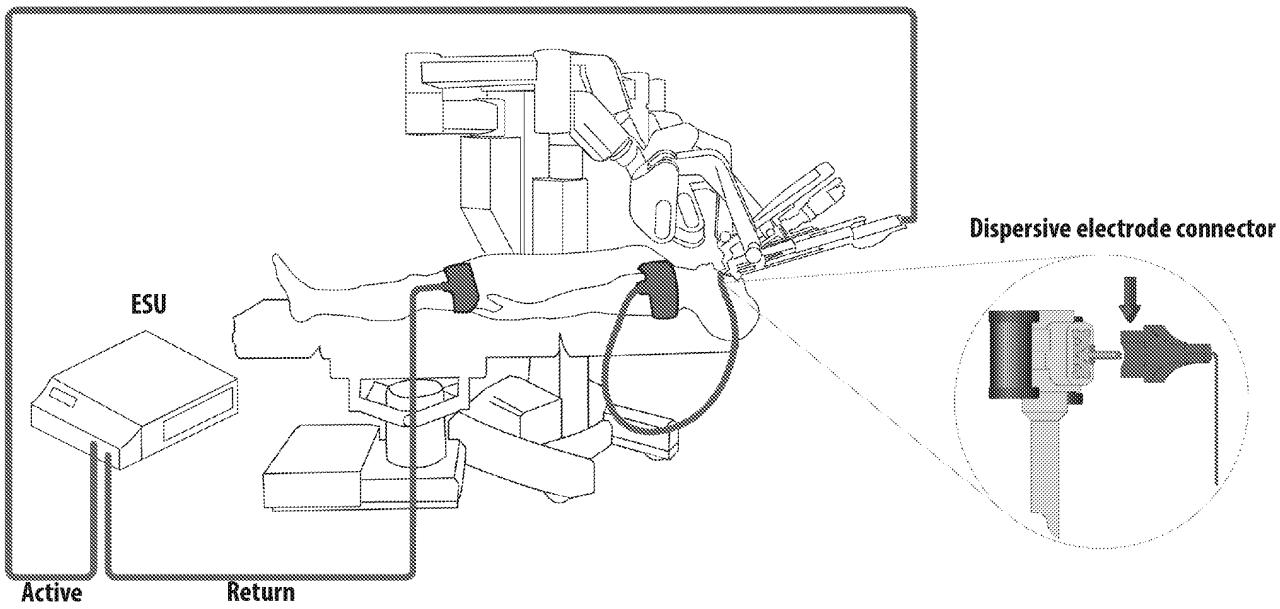

Figure 20.2 Cannula and dispersive electrode connection

5. Detachment and Removal:
   a. Disconnect the patient dispersive electrode from the cannula.
   b. To remove the cannula, clutch the instrument arm away from the patient and detach the cannula from the system.
   c. For removal of the patient dispersive electrode from the patient, please refer to the manufacturer's instructions.

End of section

21 Single Use 8 mm Cannula Seal

21.1 Introduction

This section contains instructions for use specific to the Single Use 8 mm Cannula Seal, also known as the 10/12 mm Cannula Seal.

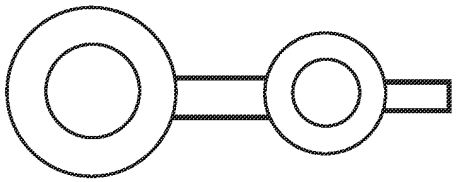

Figure 21.1 Intuitive Surgical 8 mm Cannula Seal

Note: The 8 mm Cannula Seal is sterile unless the package is opened or damaged. It is designed for single use. Do not reuse or resterilize.

CAUTION: **DO NOT RE-STERILIZE.** **DO NOT RE-USE.**

Reprocessing and/or reuse of products intended for single use only may result in degraded instrument performance or loss of functionality, and in exposure to viral, bacterial, fungal, or prionic pathogens.

CAUTION: **Do not use if package is damaged.**

CAUTION: A breach in the sterile packaging of the device indicates possible contamination. Do not use the device if the packaging is not intact.

Note: Read Knowing What Applies – Organization of this Manual (page 1-1) to understand what portions of this manual apply to any specific instrument or accessory. If information specific to an instrument or accessory is not supplied in this manual, *Intuitive* supplies it with that instrument or accessory.

Intended Use

Indications

The *Intuitive Surgical* 8 mm cannula seal system has applications in endoscopic surgery, for establishment of a port of entry for endoscopic instruments. The *Intuitive Surgical* cannula must be used in conjunction with an *Intuitive Surgical*, 8 mm seal in order to maintain pneumoperitoneum.

Contraindications

This device is contraindicated in situations where endoscopic surgery is contraindicated. In addition, this device is not intended for use except as indicated.

Device Description

The disposable seal consists of an internal valve and seal to prevent gas leakage when instruments are inserted or withdrawn. The 8 mm seal includes a built-in 5 mm converter to prevent leakage and allow insertion of instruments of different diameters than the main seal. The seal is to be assembled with the *Intuitive* cannula. To use, attach the disposable seal assembly securely to the top of the cannula. Ensure that the seal is visibly seated around the circumference of the cannula bowl. Insert the obturator through the seal into the cannula until the handle of the obturator is seated firmly against the seal, and the tip of the obturator appears at the distal end of the cannula sleeve.

⚠ WARNING: Do not insert instruments through the cannula that have outside diameters less than the seal diameter. This situation may cause release of gas and loss of pneumoperitoneum.

End of section

22 8 mm to 5 mm Cannula Reducer

22.1 Introduction

This sections provides instructions for use specific to the 8 mm to 5 mm Cannula Reducer. The Cannula Reducer consists of two components:

- The reusable 8 mm to 5 mm Cannula Reducer, PN 371051 (*da Vinci*) or PN 420019 (*da Vinci S* and *da Vinci Si*)

> **Note: This device ships non-sterile. Clean and sterilize before use.**

- The disposable 5 mm seal, PN 400161

Note: Read Knowing What Applies – Organization of this Manual (page 1-1) to understand what portions of this manual apply to any specific instrument or accessory. If information specific to an instrument or accessory is not supplied in this manual, *Intuitive* supplies it with that instrument or accessory.

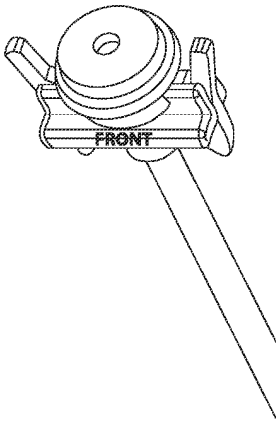

Figure 22.1 Seal attached to reducer

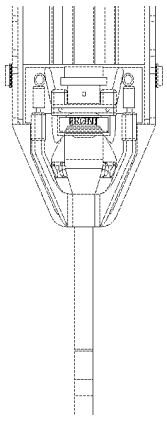

Figure 22.2 Mounted on system

Intended Use

The 8 mm to 5 mm Cannula Reducer is intended to be used with the *Intuitive Surgical da Vinci, da Vinci S* and *da Vinci Si* Systems. The system is intended to be used only by trained professionals in operating room environments.

22.2 Instructions for Use

1. Attach the seal to the reducer by aligning it axially with the reducer, and sliding the pins of the cannula reducer into the slots on the seal. Rotate the seal clockwise to lock into place. You will hear a click once the cannula seal is locked in place. See Figure 22.1.
2. The cannula and 8 mm seal should be mounted on the appropriate system. Slide the cannula section of the reducer into the 8 mm seal. The front of the reducer should be facing away from the Instrument Arm. Slide the reducer down until the latches lock onto the cannula. See Figure 22.2.
3. 5 mm instruments may now be used by installing them onto the system, through the 5 mm seal in the reducer. Instruments may be removed from the system normally.
4. To remove the reducer from the system, squeeze the latch levers and lift the reducer out of the 8 mm seal.

End of section

23 Endoscope Cannula Mounts

23.1 Introduction

This section provides instructions for use specific to the endoscope cannula mounts used with the *da Vinci*, *da Vinci S*, and *da Vinci Si* surgical systems.

Note: The Endoscope Cannula Mounts for the *da Vinci* Surgical System are shipped non-sterile. Clean and sterilize before use.

Note: Read Knowing What Applies – Organization of this Manual (page 1-1) to understand what portions of this manual apply to any specific instrument or accessory. If information specific to an instrument or accessory is not supplied in this manual, *Intuitive* supplies it with that instrument or accessory.

Intended Use

The *Intuitive Surgical* Endoscope Cannula Mounts are designed for the camera arm of the *da Vinci*, *da Vinci S*, and *da Vinci Si* surgical systems. The Endoscope Cannula Mount attaches to a disposable cannula that serves as the port of entry for *da Vinci* Surgical System endoscopes. The Endoscope Cannula Mount for the *da Vinci* Surgical System is shipped non-sterile, and must be cleaned and sterilized before each procedure.

The Endoscope Cannula Mount for the *da Vinci S* and *da Vinci Si* surgical systems ships as part of the system, assembled to the camera arm, and should remain assembled to the camera arm except when it is damaged and requires replacement. It ships non-sterile and should not be sterilized, since it is to be draped by the camera arm drape during procedures.

Contraindications

This device is not intended for use when minimally invasive techniques are contraindicated.

Device Description

The *Intuitive Surgical* Endoscope Cannula Mount is manufactured in four configurations for validated third party 12 mm and 8.5 mm cannulae. All cannulae used with the system must be at least 100 mm in length to properly position the camera arm remote center.

Table 23-1 12 mm Endoscope Cannula Mount Configurations

Manufacturer	Validated 12 mm Cannulae	*da Vinci* Endoscope Cannula Mount PN	*da Vinci* S/Si Endoscope Cannula Mount PN
Ethicon EndoSurgery 800-873-3636 www.ethiconendo.com	ENDOPATH® XCEL™ (B12LT)[a]	370269	371521
Taut (Teleflex Medical) 866-246-6990 www.teleflexmedical.com	ADAPt™ Laparoscopic Port (41210, 41213, 41233)[b] Weck Vista™ (40591213, 40591213R, 405933L)	NA	
SurgiQuest, Inc. 877-509-3947 www.surgiquest.com	12 mm Access Port with Bladeless Optical Tip Trocar (iAS12-120E)		
Covidien (Autosuture, US Surgical) 800-722-8772 www.covidien.com	VersaStep™ PLUS (VS101012P) Versaport™ Plus (179096P) Bluntport™ Plus (176626P, 179075P)	370626	371454
	Versaport™ Plus Bladeless (NB12STF)	NA	371528
Applied Medical 800-282-2212 www.appliedmed.com	Kii® Z-Thread (CTF71, CTR71, CTB71, CTR72) Kii® Advanced Fixation (CFF71, CFR71, CFB71)	NA	371528
Stryker 800-624-4422 www.stryker.com/passport	Passport® Blunt Tip Trocar, 12 x 150 mm, Robotic Camera Port, Stopcock (0260-512-150)		
SurgiQuest, Inc. 877-509-3947 www.surgiquest.com	12 mm Access Port with Bladeless Optical Tip Trocar (iAS12-120, iAS12-150)	371394	371512
Intuitive Surgical 888-409-4774 www.intuitivesurgical.com	12 mm Balloon Port (400193)[b]		

a. The seal cap on the ENDOPATH XCEL cannula may become detached if the cannula cap comes into contact with the skin and the endoscope arm is fully pitched. This may result in a sudden loss of insufflation.
b. Discontinued by manufacturer.

Note: Rotate insufflation tubing to the side of the endoscope cannula. This protects the patient's body wall when the camera arm is fully pitched.

Note: When placing an endoscope cannula in the patient, ensure that the top of the endoscope cannula mount is approximately 7.9 cm from the center of the body wall, regardless of the length of the cannula, retention balloons, or other features. The cannula will rotate around this point (the remote center), minimizing the torque on the patient.

Table 23-2 8.5 mm Endoscope Cannula Mount Configurations

Manufacturer	Validated 8.5 mm Cannulae	*da Vinci* Endoscope Cannula Mount PN	*da Vinci* S/Si Endoscope Cannula Mount PN
Stryker 800-624-4422 www.stryker.com/passport	Passport® SmartTip™, Trocar, 8.5 x 100 mm, Robotic Camera Port, Stopcock (0260-285-100)	370629	371521
Intuitive Surgical 888-409-4774 www.intuitivesurgical.com	8.5 mm Endoscope Cannula (400263, 420260)		
SurgiQuest, Inc. 877-509-3947 www.surgiquest.com	8 mm Access Port with Bladeless Optical Tip Trocar (iAS8-120LP)	NA	

⚠ **CAUTION: Using a non-validated cannula, or a validated cannula with an incorrect cannula mount, may damage the cannula mount.**

23.2 *da Vinci* Surgical System Endoscope Cannula Mount

As depicted in Figure 23.1, the *da Vinci* Surgical System endoscope cannula mount consists of three main parts: the latch, the engagement pin and the alignment pin. The available endoscope cannula mount configurations are differentiated by marking on the front of the latch: either "ETH" (PN 370269, 12 mm), "USS" or "COV" (PN 370626, 12 mm), or "BALLOON" (PN 371394, 12 mm).

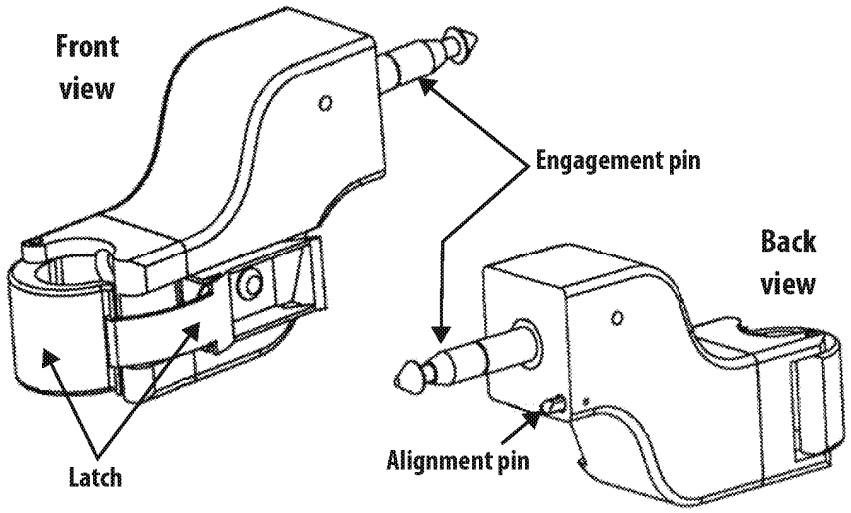

Figure 23.1 Endoscope cannula mount, front and back views

Instructions for Use

⚠ **WARNING: Verify that the endoscope cannula mount is matched to the appropriate disposable validated third party 12 mm cannula you are using.**

Fixation to the Camera Arm

1. Once the camera arm is covered with the sterile drape, align the engagement pin on the endoscope cannula mount with the reinforced hole at the bottom of the drape.

2. Make sure the alignment pin is aligned with the alignment hole in the drape and the camera arm.
3. Securely snap the endoscope cannula mount into place.

Fixation of the Cannula

1. Attach the cannula to the endoscope cannula mount by securing the latch.
2. To ensure the remote center of the cannula is properly positioned, the cannula should be attached at a point immediately below the cannula housing (see Figure 23.2 below).

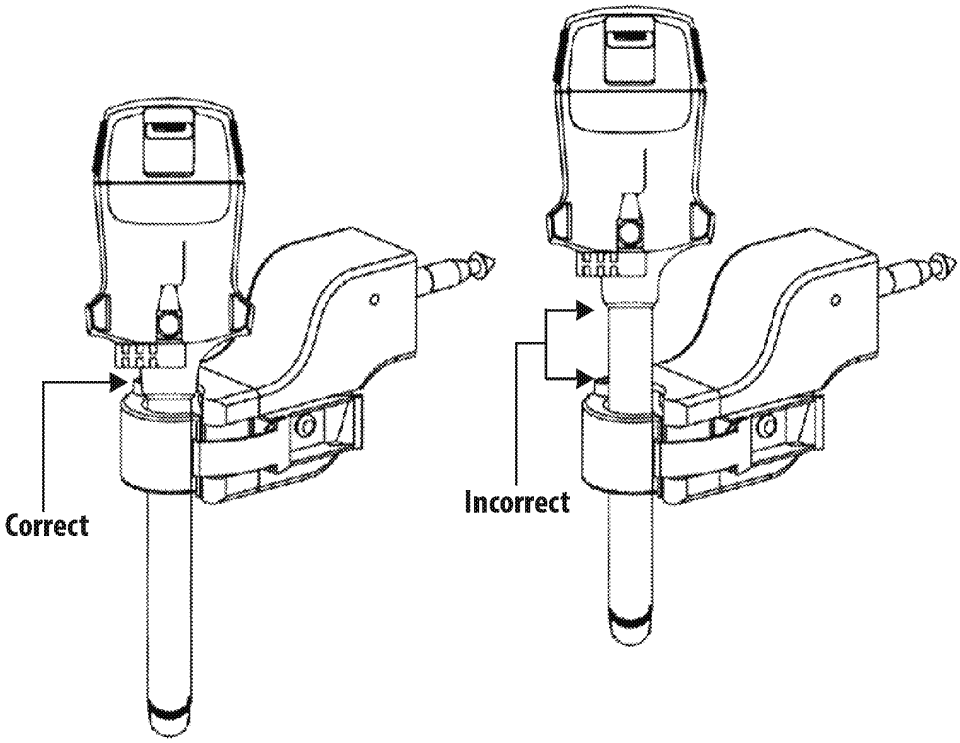

Figure 23.2 Proper cannula fixation

Removal of the Cannula

To detach the cannula, open the latch on the endoscope cannula mount.

Removal from the Camera Arm

To detach the endoscope cannula mount from the camera arm, depress the release button on the camera arm and pull the endoscope cannula mount straight out without any rotation.

23.3 *da Vinci S* and *da Vinci Si* Surgical System Endoscope Cannula Mount

As depicted in Figure 23.3, the *da Vinci S/Si* endoscope cannula mount consists of four main parts: the clamping levers, the clamp, the engagement pin and the alignment pin. The available endoscope cannula mount configurations are differentiated by marking on the side of the clamp: either "ETH" (PN 371521, 12 mm), "USS" or "COV" (PN 371454, 12 mm), "BALLOON" (PN 371512, 12 mm), or "AM" (PN 371528).

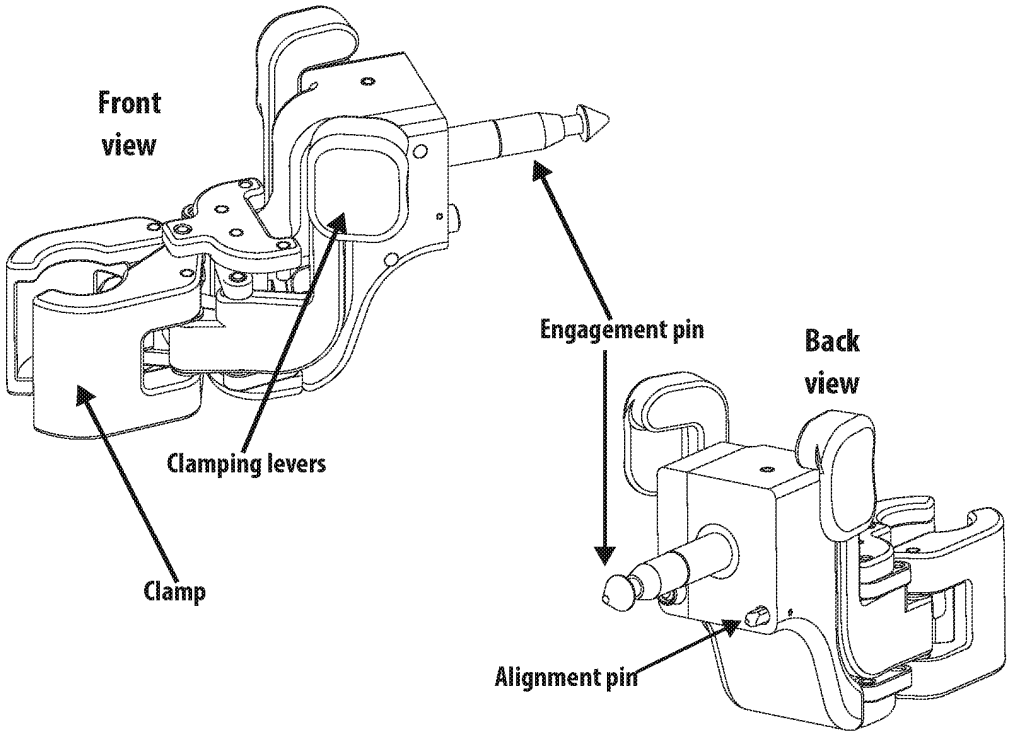

Figure 23.3 Endoscope cannula mount for da Vinci S and da Vinci Si, front and back views

Instructions for Use

WARNING: Verify that the endoscope cannula mount is matched to the appropriate disposable validated third party 12 mm cannula you are using.

Note: The endoscope cannula mount for *da Vinci S/Si* is installed on the system when delivered. Fixation and removal instructions are applicable only for replacing a damaged cannula mount, or for using a clamp for a different third party cannula. During normal use, the endoscope cannula mount should remain attached to the camera arm.

Fixation to the Camera Arm

1. Align the engagement pin on the endoscope cannula mount with the hole on the camera arm.
2. Make sure the alignment pin is aligned with the alignment hole in the camera arm.
3. Press the endoscope cannula mount into the camera arm until it locks in place. You will hear a click once the cannula mount is secured.

Fixation of the Cannula

1. Drape the camera arm with the camera arm drape.
2. Attach the cannula to the endoscope cannula mount by squeezing the clamping levers.
3. To ensure the remote center of the cannula is properly positioned, the cannula should be attached at a point immediately below the cannula housing.

Removal of the Cannula

To detach the cannula, spread open the clamping levers.

Removal from the Camera Arm

To detach the endoscope cannula mount from the camera arm, depress the release button on the camera arm and pull the endoscope cannula mount straight out without any rotation.

End of section

24 *da Vinci* and *da Vinci S* Light Guide

24.1 Introduction

This section provides instructions specific to use of the Light Guide in conjunction with the *da Vinci* and *da Vinci S* surgical systems.

Note: Read Knowing What Applies – Organization of this Manual (page 1-1) to understand what portions of this manual apply to any specific instrument or accessory. If information specific to an instrument or accessory is not supplied in this manual, *Intuitive* supplies it with that instrument or accessory.

CE

Light Guide Information

The Light Guide PN 951026 is made by Schoelly Fiberoptic and distributed by *Intuitive Surgical*.

Schoelly Fiberoptic GmbH
Robert-Koch-Str. 1-3
79211 Denzlingen
GERMANY

Distributed by:
Intuitive Surgical
1266 Kifer Road, Sunnyvale, California 94086 • USA
Intuitive Surgical Sàrl
1, chemin des Mûriers, 1170 Aubonne Switzerland
Customer Service from USA 1.800.876.1310
Customer Service from Europe +800.0821.2020
Manufactured in Germany.

Intended Use

This light guide is designed for transmission of light between the Intuitive Surgical, Inc. (ISI) Light Source and Endoscopic Camera for illumination of the surgical site during therapeutic applications. It is intended to be used only in a medical facility, by trained medical professionals, in accordance with the *da Vinci, da Vinci S* and Light Source user manuals. Do not use it for any other purpose.

Light Guide Care

Because fiber optic guides are made of glass, they are delicate optical instruments and require careful handling. Follow the guidelines on this page for best results.

- Never stretch, kink or bend the guide. Avoid getting the guide caught in doors and drawers. Never coil the guide into a diameter tighter than 6 inches or 15 cm. Never apply pressure with a sharp object to the guide. If internal glass fiber breakage exceeds 15%, the guide's light output will noticeably diminish.
- Do not modify or change the mechanical structure of the guide or its adapters. The guide is designed for optimal performance as manufactured.

- Avoid scratching or dropping the polished fiber surfaces of the guide ends during handling. Damaging the polished surface of the guide ends will reduce the guide's light output as well.
- Any inadvertent cut or puncture renders the light guide cable unsafe, and it should be taken out of service immediately.

24.2 Instructions for Use

- Inspect the guide for physical damage and check its light transmission efficiency before each use. View one light guide end while exposing the other end to ambient light (not the illuminator). Black dots indicate broken fibers. Replace the guide if more than 15% is black. Never use a damaged light guide.
- Never leave the light guide unattended while it transmits light from the illuminator.

Note: Failure to use and care for the light guide in accordance with these guidelines may void all warranties, expressed or implied, if any, accompanying the light guides.

End of section

25 Sterilization Trays

25.1 Introduction

This section contains instructions for use specific to the *Intuitive Surgical* Instrument and Accessory Sterilization Trays.

Note: Read Knowing What Applies – Organization of this Manual (page 1-1) to understand what portions of this manual apply to any specific instrument or accessory. If information specific to an instrument or accessory is not supplied in this manual, *Intuitive* supplies it with that instrument or accessory.

Intended Use

Intuitive Surgical Instrument and Accessory Sterilization Trays are intended for the protection, organization and delivery to the surgical field of *Intuitive Surgical EndoWrist* instruments and *Intuitive Surgical* reusable accessories ***only***, as listed in Table 25-1 below.

Table 25-1 List of Compatible Devices

Intended Content	Description
Intuitive Surgical EndoWrist Instrument	*da Vinci* & *da Vinci S/Si* families of 8 mm and 5 mm *EndoWrist* instruments
Intuitive Surgical Reusable Accessories	*da Vinci* & *da Vinci S/Si* families of 8 mm and 5 mm *EndoWrist* accessories, including cannulae, obturators, cannula mounts, sterile adapters, etc.

Use with Sterilization Wrap

The trays are not intended to maintain sterility by themselves. They are designed to facilitate the pre-vacuum autoclave sterilization process when used in conjunction with a wrapping material (FDA cleared sterilization wrap). Wrapping materials are designed to allow air removal, steam penetration/evacuation and maintain the sterility of the internal components. When using *Intuitive Surgical* sterilization trays in conjunction a sterilization wrap, use the sterilization process parameters specified here: see Sterilization Process Parameters below.

Apart from sterilization using *Intuitive Surgical* sterilization trays, refer to the Reprocessing Instructions (PN 550875) for cleaning, disinfection, and sterilization of reusable instruments, accessories, and components.

Table 25-2 Information on CE Marking of OEM Devices

Part Number (PN) and Products				Distributor:
PN 400220 Single Instrument Tray PN 400221 Instrument Tray PN 400222 Accessory Tray PN 400223 Procedure Tray	Symmetry Medical Inc., 253 Abby Rd., Manchester, NH 03103-3300, U.S.A.	SymmetryMedical, Parc d'Avités du Moulin, 139 Avenue Clément Ader, 59118 Warnbrechies, FRANCE	CE	Intuitive Surgical1266 Kifer Road, Sunnyvale, California 94086 • USA Intuitive Surgical Sàrl, 1, chemin des Mûriers, 1170 Aubonne, SWITZERLAND Customer Service from USA 1.800.876.1310 Customer Service from Europe +800.0821.2020

Device Description

Table 25-3 describes the available *Intuitive Surgical* instrument and accessory sterilization trays.

Table 25-3 Intuitive Surgical Instrument and Accessory Sterilization Trays

Tray Name (PN)	Intended Content (Only *Intuitive Surgical* reusable accessories and *EndoWrist* instruments)	Dimensions (L x W x H)	Weight UL: Unloaded FL: Fully Loaded
Single Instrument Tray (PN: 400220)	One *EndoWrist* instrument	62 x 9.4 x 4.3 cm (24.4" x 3.7" x 1.7")	UL: 0.45 kg (1 lb) FL: 0.91 kg (2 lb)
Instrument Tray (PN: 400221)	Eight *EndoWrist* instruments	61.5 x 24.9 x 8.6 cm (24.2" x 9.8" x 3.4"	UL: 0.45 kg (1 lb) FL: 0.91 kg (2 lb)
Accessory Tray (PN: 400222)	*Intuitive Surgical* accessories	53.8 x 24.9 x 8.9 cm (21.2" x 9.8" x 3.5")	UL: 2.27 kg (5 lb) FL: 5.9 kg (13 lb)
Procedure Tray (PN: 400223)	Eight *EndoWrist* instruments & accessories	61.5 x 24.9 x 14 cm (24.2" x 9.8" x 5.5")	UL: 3.18 kg (7 lb) FL: 9.53 kg (21 lb)

Note: The internal surface of the lid of each tray contains graphics of the *Intuitive Surgical EndoWrist* instruments and accessories that are intended to be enclosed in the tray.

- Do not place any additional devices in the tray, since this may impact the efficacy of the sterilization process.
- Place each device in its designated slot for effective protection, organization and sterilization of the enclosed components.

Contraindications

The Instrument and Accessory trays should not be loaded more than depicted in the graphics inside the cover. The trays are intended to be used with the designated *Intuitive Surgical* instruments and accessories only.

⚠ **CAUTION: Stacking of sterilization trays and overloading the trays will adversely affect sterilization and drying effectiveness. Stacking trays in the autoclave chamber is *not* recommended.**

25.2 Instructions for Use

Inspection Prior to Use

Always inspect for cleanliness or damage before use. Make sure all latches and handles are secure and in working order. ***Do not*** overload trays and place all items in the designated location ***only***.

Recommended Care

Intuitive recommends cleaning the trays manually using a mild enzymatic cleaning solution. Wet a soft sponge or cloth with the cleaning solution and wipe all areas of the tray, then rinse thoroughly to remove any detergent or chemical residue. Do not use solvents, abrasive cleaners, metal brushes or abrasive pads to clean any part of the trays.

Sterilization Process Parameters

Wrapped sterilization trays have been validated for the following sterilization parameters.

Cycle:	Pre-vacuum
Temperature:	270-272 ºF (132-134 ºC)
Minimum exposure time for the U.S:.	4 minutes
Minimum exposure time for countries following European guidelines:	3 minutes
Minimum dry time:	30 minutes

Except for the sterilization process parameters listed here, follow the applicable cleaning, disinfection and sterilization instructions found in the Reprocessing Instructions (PN 550875). In addition, when using the tray in conjunction with a wrap, *Intuitive* recommends following the wrap manufacturer's instructions for procedures prior to sterilization, to maintain sterility of the internal components/items and for proper, aseptic presentation to the surgical field.

Special Instructions for Procedure Tray (PN 400223)

To ensure proper closure, verify that any loose items in the generic pocket do not protrude above the side walls and the sterile adapters are not angled outward in such a way that they interfere with the instrument insert.

Precautions

- Do not load cases into the autoclave on sides or upside down. Always load cases on carts or shelves so that the lid is always facing upward. This will allow for proper drying since the trays are designed to drain in this position.
- Do not use non-absorbent tray liners or mats (i.e., silicone or plastic), as they can cause condensation to pool.

- After the autoclave door is opened, all trays must be allowed to cool thoroughly. Place trays on a rack or shelf with linen cover until cooling is complete. The potential for condensation may increase if the case is not allowed to cool properly.

If you observe condensation, check to ensure the previous steps were followed. Also verify the steam being used for sterilization processing has a quality of more than 97%, and that the sterilizers have been inspected for routine maintenance according to manufacturer recommendations.

Symmetry Medical
253 Abby Road
Manchester, NH 03103 USA
www.polyvac.com

Distributed by: Intuitive Surgical

Manufactured in the USA

End of section

A Appendix A: Symbols Defined

The following symbols may appear on packaging labels for instruments or accessories and have the meaning indicated.

 • Do not use if package is damaged	 or  • Not made with natural rubber latex	 • Contains or presence of natural rubber latex
 • Uses. The adjacent number indicates the number of procedures after which a device expires.	 • Fires. The adjacent number indicates the number of times a device can be fired before it expires.	 • Closures. The adjacent number indicates the number of times an installed clip applier instrument can fully close its jaws before it expires.
 • Quantity	 • Version	 • Peel to open

End of section

B Appendix B: Natural Rubber Latex

The following *Intuitive Surgical* products referenced in this manual are not made with natural rubber latex:

- Camera Arm Drape (PN 420279)
- 8 mm Cannula Seal (PN 400077)
- CardioVac Tubing for *EndoWrist* Stabilizer (PN 420186)
- Vacuum Source Tubing for *EndoWrist* Stabilizer (PN 420187)
- Clearfield Tubing for *EndoWrist* Stabilizer (PN 420185)
- Instrument Arm Drape (PN 420015)
- 8.5-13mm Cannula Seal (PN 420206)
- Tip Cover Accessory (PN 400180)
- *EndoWrist One* Suction/Irrigator (PN 410299)
- Cautery Hook Tip, 5 mm (PN 400156)
- Cautery Spatula Tip, 5 mm (PN 400160)

End